

US3672407 (Prod: Coastal Carolina Research Center)

Generated By: KC Joubran

Generated On: 11 Aug 2021 23:01:47

All time stamps listed in this document are displayed in GMT

US3672407

Form: Participant Creation

Data signed: (b) (4) 05 Mar 2021 18:37:52

Generated On: 11 Aug 2021 23:01:47

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[Participant ID](#)

US3672407

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

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US3672407

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 21:10:40

Generated On: 11 Aug 2021 23:01:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 17 Feb 2021 21:10:40

Generated On: 11 Aug 2021 23:01:47

Date of Birth (MMM yyyy)	(b) (6) 1979
Age	41
Age Units	YEARS
Age (Derived)	41
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 17 Feb 2021 21:10:40

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 17 Feb 2021 21:10:40

Generated On: 11 Aug 2021 23:01:47

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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 21:10:40

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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 21:10:40

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Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 17 Feb 2021 21:10:40

Generated On: 11 Aug 2021 23:01:47

Condition	AUGMENTIN ALLERGY- NAUSEA
Start date (dd MMM yyyy)	UN UNK 1997
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 1997
Start Year (derived)	1997
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 17 Feb 2021 21:10:40

Generated On: 11 Aug 2021 23:01:47

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 17 Feb 2021 21:10:40

Generated On: 11 Aug 2021 23:01:47

Condition	HERPES GENITALIS
Start date (dd MMM yyyy)	17 JUN 2014
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)	JUN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 21:10:40

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 SEP 2020
Time of assessment (00:00-23:59)	14:50 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 14:50
Height (xxx.x)	166 cm
Weight (xxx.x)	88 kg
BMI (xxx.x)	31.93497 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 checked="" type="radio"/>
If Other, specify	ND - Not Done
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 21:10:40

Generated On: 11 Aug 2021 23:01:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 17 Feb 2021 21:10:40

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Date of assessment (dd MMM yyyy) 03 SEP 2020

Is the participant of childbearing potential? Yes ☒  
No ☐

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

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

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 17 Feb 2021 21:10:40

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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> )	03 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 21:10:40

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**Occupational Risk**

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**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 21:10:40

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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 21:10:40

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Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 17 Feb 2021 21:10:40

Generated On: 11 Aug 2021 23:01:47

What was the date of randomization? (dd MMM yyyy) 03 SEP 2020

What was the participant's randomization number? 111292

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 21:10:40

Generated On: 11 Aug 2021 23:01:47

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 21:10:40

Generated On: 11 Aug 2021 23:01:47

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)	03 SEP 2020
Time of assessment (00:00-23:59)	14:50 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 14:50
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)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 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 21:10:40

Generated On: 11 Aug 2021 23:01:47

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)	03 SEP 2020
Time of assessment (00:00-23:59)	15:52 (24 HR)
Vital Signs Date and Time (derived)	03 SEP 2020 15:52
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)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 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 21:10:40

Generated On: 11 Aug 2021 23:01:47

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 21:10:40

Generated On: 11 Aug 2021 23:01:47

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 21:10:40

Generated On: 11 Aug 2021 23:01:47

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) 3 SEP 2020

What was the treatment time? (00:00-23:59) 15:21 (24 HR)

Treatment Date and Time (derived) 3 SEP 2020 15:21

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 21:10:40

Generated On: 11 Aug 2021 23:01:47

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

03 SEP 2020

Collection time (00:00-23:59)

14:58 (24 HR)

Collection date and time (derived)

03 SEP 2020 14:58

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 21:10:40

Generated On: 11 Aug 2021 23:01:47

Collection date (dd MMM yyyy)			03 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:38	03 SEP 2020 14:38
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:10:40

Generated On: 11 Aug 2021 23:01:47

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 23:01:47

**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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 15:52

PC Open Date & Time

03 SEP 2020 15:41

PC Close Date & Time

03 SEP 2020 18:11

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 23:01:47

**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

98.5 °F

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

Yes ☐  
No ☒

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

PC Time Stamp	03 SEP 2020 19:07
PC Open Date & Time	03 SEP 2020 19:06
PC Close Date & Time	04 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 13:09

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

05 SEP 2020 12:01

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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

06 SEP 2020 18:13

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 23:01:47

**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

98.8 °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

07 SEP 2020 18:56

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

09 SEP 2020 10:43

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

09 SEP 2020 20:11

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:01:47

**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

03 SEP 2020 15:53

PC Open Date & Time

03 SEP 2020 15:41

PC Close Date & Time

03 SEP 2020 18:11

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:01:47

**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

03 SEP 2020 19:07

PC Open Date & Time

03 SEP 2020 19:06

PC Close Date & Time

04 SEP 2020 11:59

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:01:47

**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

04 SEP 2020 13:09

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:01:47

**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

05 SEP 2020 12:02

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59



US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:01:47

**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

06 SEP 2020 18:13

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:01:47

**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

07 SEP 2020 18:56

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:01:47

**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

09 SEP 2020 10:43

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:01:47

**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

09 SEP 2020 20:12

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:01:47

**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 ☐

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:01:47

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 15:54
PC Open Date & Time	03 SEP 2020 15:41
PC Close Date & Time	03 SEP 2020 18:11

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:01:47

**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 ☐

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:01:47

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 19:08
PC Open Date & Time	03 SEP 2020 19:06
PC Close Date & Time	04 SEP 2020 11:59



US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 23:01:47

**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 ☒

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 23:01:47

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 13:10
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 23:01:47

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 ☒

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 23:01:47

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 12:02
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 23:01:47

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 18:13
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 23:01:47

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 ☒

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 23:01:47

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 18:56
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59



US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

DAY 6

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 23:01:47

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 10:43
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 23:01:47

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 ☒

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 23:01:47

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 20:12
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3672407

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 21:10:40

Generated On: 11 Aug 2021 23:01:47

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3672407

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:10:40

Generated On: 11 Aug 2021 23:01:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672407

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 21:10:40

Generated On: 11 Aug 2021 23:01:47

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 17 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3672407

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:10:40

Generated On: 11 Aug 2021 23:01:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3672407

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 21:10:40

Generated On: 11 Aug 2021 23:01:47

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3672407

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:10:40

Generated On: 11 Aug 2021 23:01:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672407

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 21:10:56

Generated On: 11 Aug 2021 23:01:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 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

US3672407

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 21:10:56

Generated On: 11 Aug 2021 23:01:47

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)	29 SEP 2020
Time of assessment (00:00-23:59)	12:22 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 12:22
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)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3672407

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 21:10:56

Generated On: 11 Aug 2021 23:01:47

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

US3672407

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 21:10:56

Generated On: 11 Aug 2021 23:01:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 SEP 2020

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

US3672407

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 17 Feb 2021 21:10:56

Generated On: 11 Aug 2021 23:01:47

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	29 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)	

US3672407

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 21:10:40

Generated On: 11 Aug 2021 23:01:47

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 DUE TO AE ON 7 SEP 2020

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? \_\_\_\_\_



US3672407

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 21:10:40

Generated On: 11 Aug 2021 23:01:47

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 SEP 2020

Collection time (00:00-23:59)

13:28 (24 HR)

Collection date and time (derived)

29 SEP 2020 13:28

US3672407

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 21:10:40

Generated On: 11 Aug 2021 23:01:47

Collection date (dd MMM yyyy)			29 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:03	29 SEP 2020 13:03
Nasopharyngeal Swab 2	No		

US3672407

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:10:40

Generated On: 11 Aug 2021 23:01:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672407

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 21:10:40

Generated On: 11 Aug 2021 23:01:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3672407

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:10:40

Generated On: 11 Aug 2021 23:01:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672407

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 21:10:40

Generated On: 11 Aug 2021 23:01:47

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 13 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3672407

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:10:40

Generated On: 11 Aug 2021 23:01:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672407

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 21:10:40

Generated On: 11 Aug 2021 23:01:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3672407

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:10:40

Generated On: 11 Aug 2021 23:01:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672407

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 21:10:56

Generated On: 11 Aug 2021 23:01:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3672407

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 21:10:56

Generated On: 11 Aug 2021 23:01:47

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 OCT 2020
Time of assessment (00:00-23:59)	12:18 (24 HR)
Vital Signs Date and Time (derived)	26 OCT 2020 12:18
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3672407

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 21:10:56

Generated On: 11 Aug 2021 23:01:47

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.*

US3672407

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 21:10:56

Generated On: 11 Aug 2021 23:01:47

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 OCT 2020

Collection time (00:00-23:59)

12:48 (24 HR)

Collection date and time (derived)

26 OCT 2020 12:48

US3672407

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:10:56

Generated On: 11 Aug 2021 23:01:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672407

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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 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"/>

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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

Date and time of submission

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59



US3672407

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3672407

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Close Date & Time](#)

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25 NOV 2020 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

[Patient Cloud Open Date & Time](#)

28 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2020 23:59



US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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 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"/>

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	05 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 DEC 2020 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 DEC 2020 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

DAY 110

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

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

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

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Open Date & Time](#)

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19 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

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23 DEC 2020 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Close Date & Time](#)

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30 DEC 2020 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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 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"/>

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	02 JAN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 JAN 2021 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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"/>

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	09 JAN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 JAN 2021 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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"/>

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Open Date & Time](#)

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16 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 JAN 2021 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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="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"/>

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 JAN 2021 23:59



US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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="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"/>

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2021 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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"/>

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

[Patient Cloud Close Date & Time](#)

10 FEB 2021 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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="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"/>

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Open Date & Time](#)

13 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 FEB 2021 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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 <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"/>

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Close Date & Time](#)

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24 FEB 2021 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAR 2021 07:47:55

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

**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

06 MAR 2021 07:53:42

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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	13 MAR 2021 11:51:56
Patient Cloud Open Date & Time	13 MAR 2021 00:01
Patient Cloud Close Date & Time	17 MAR 2021 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 MAR 2021 05:02:28

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 MAR 2021 07:52:52

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

**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

03 APR 2021 06:07:21

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

**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

10 APR 2021 05:12:48

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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 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"/>



**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

[Patient Cloud Close Date & Time](#)

21 APR 2021 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

**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

28 APR 2021 08:54:55

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

<b>TIMEPOINT</b>	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 MAY 2021 04:51:15
Patient Cloud Open Date & Time	01 MAY 2021 00:01
Patient Cloud Close Date & Time	05 MAY 2021 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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 <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"/>

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Close Date & Time](#)

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12 MAY 2021 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

**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 ☐

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Open Date & Time](#)

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15 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2021 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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"/>



**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Open Date & Time](#)

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29 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 JUN 2021 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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



**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Open Date & Time](#)

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19 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 JUN 2021 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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"/>

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	26 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 JUN 2021 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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"/>

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

10 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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"/>



**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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"/>

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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"/>

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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="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"/>



**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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"/>

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

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

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

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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°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"/>



**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Open Date & Time](#)

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18 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 SEP 2021 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

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

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

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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



**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	09 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 OCT 2021 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Open Date & Time](#)

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16 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 OCT 2021 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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"/>

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 OCT 2021 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>



**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Open Date & Time](#)

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06 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 NOV 2021 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	20 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 NOV 2021 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	27 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	01 DEC 2021 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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="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"/>

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	25 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 DEC 2021 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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"/>



**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Open Date & Time](#)

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01 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 JAN 2022 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

DAY 495

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

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

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

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

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

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

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

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

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Close Date & Time](#)

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12 JAN 2022 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

**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 ☐

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Open Date & Time](#)

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22 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 JAN 2022 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

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

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



**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Open Date & Time](#)

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29 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 FEB 2022 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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"/>

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Open Date & Time](#)

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05 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 FEB 2022 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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12 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 FEB 2022 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Open Date & Time](#)

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19 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 FEB 2022 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

**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 ☐



**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Close Date & Time](#)

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02 MAR 2022 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

**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 ☐

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Open Date & Time](#)

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05 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAR 2022 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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12 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAR 2022 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

**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 ☐

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

**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 ☐



**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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"/>

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

**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 ☐

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Open Date & Time](#)

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09 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 APR 2022 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

**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 ☐

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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"/>



**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Open Date & Time](#)

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23 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 APR 2022 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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"/>

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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="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"/>

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Open Date & Time](#)

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07 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAY 2022 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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"/>

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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="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"/>



**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Close Date & Time](#)

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25 MAY 2022 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Close Date & Time](#)

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01 JUN 2022 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Close Date & Time](#)

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08 JUN 2022 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

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

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

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Open Date & Time](#)

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11 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 JUN 2022 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

**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 ☐

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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"/>

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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 ☐

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Open Date & Time](#)

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09 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 JUL 2022 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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"/>



**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Open Date & Time](#)

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16 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 JUL 2022 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°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"/>

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Open Date & Time](#)

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23 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 JUL 2022 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Close Date & Time](#)

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10 AUG 2022 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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



**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Open Date & Time](#)

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13 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 AUG 2022 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

**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 ☐ 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 ☐

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Close Date & Time](#)

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24 AUG 2022 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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



**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Open Date & Time](#)

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10 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 SEP 2022 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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"/>

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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="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"/>

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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24 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 SEP 2022 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Open Date & Time](#)

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01 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 OCT 2022 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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="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"/>



**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

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

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

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 OCT 2022 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

**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 ☐

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Open Date & Time](#)

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22 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 OCT 2022 23:59

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US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3672407

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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="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"/>



**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

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[Patient Cloud Open Date & Time](#)

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05 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 NOV 2022 23:59

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US3672407

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 11 Aug 2021 23:01:47

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		03 MAR 2021 07:47:32

US3672407

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:37:53

Generated On: 11 Aug 2021 23:01:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3672407

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:37:53

Generated On: 11 Aug 2021 23:01:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672407

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:37:53

Generated On: 11 Aug 2021 23:01:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3672407

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:37:53

Generated On: 11 Aug 2021 23:01:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672407

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:37:53

Generated On: 11 Aug 2021 23:01:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3672407

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:37:53

Generated On: 11 Aug 2021 23:01:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3672407

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:37:53

Generated On: 11 Aug 2021 23:01:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3672407

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:37:53

Generated On: 11 Aug 2021 23:01:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672407

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 15:34:44

Generated On: 11 Aug 2021 23:01:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3672407

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 15:34:44

Generated On: 11 Aug 2021 23:01:47

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) \_\_\_\_\_

US3672407

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 15:34:44

Generated On: 11 Aug 2021 23:01:47

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.*

US3672407

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 15:34:44

Generated On: 11 Aug 2021 23:01:47

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

06 APR 2021

Collection time (00:00-23:59)

10:02 (24 HR)

Collection date and time (derived)

06 APR 2021 10:02

**US3672407**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:01:47**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3672407

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 23:01:47

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



**US3672407**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 11 Aug 2021 23:01:47**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3672407

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

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 18:37:53

Generated On: 11 Aug 2021 23:01:47

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

Visit date (dd MMM yyyy)	28 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3672407

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 15:34:44

Generated On: 11 Aug 2021 23:01:47

Date of updated informed consent ( <i>dd MMM yyyy</i> )	28 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	28 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input 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

US3672407

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Apr 2021 15:34:44

Generated On: 11 Aug 2021 23:01:47

Height	
Weight	
BMI (xxx.x)	

US3672407

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Apr 2021 15:34:44

Generated On: 11 Aug 2021 23:01:47

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 JAN 2021
Time of assessment (00:00-23:59)	10:26 (24 HR)
Vital Signs Date and Time (derived)	28 JAN 2021 10:26
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)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3672407

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Apr 2021 15:34:44

Generated On: 11 Aug 2021 23:01:47

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 JAN 2021
Time of assessment (00:00-23:59)	11:21 (24 HR)
Vital Signs Date and Time (derived)	28 JAN 2021 11:21
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)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3672407

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

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 18:37:53

Generated On: 11 Aug 2021 23:01:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 JAN 2021

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

US3672407

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

Form: Pregnancy Test

Data signed: (b) (4) 05 Mar 2021 18:37:53

Generated On: 11 Aug 2021 23:01:47

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	28 JAN 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	



US3672407

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

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 18:37:53

Generated On: 11 Aug 2021 23:01:47

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) 28 JAN 2021

What was the treatment time? (00:00-23:59) 10:50 (24 HR)

Treatment Date and Time (derived) 28 JAN 2021 10:50

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

What was the frequency of the study treatment dosing? ONCE

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

US3672407

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 18:37:53

Generated On: 11 Aug 2021 23:01:47

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 JAN 2021

Collection time (00:00-23:59)

10:21 (24 HR)

Collection date and time (derived)

28 JAN 2021 10:21

US3672407

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Mar 2021 18:37:53

Generated On: 11 Aug 2021 23:01:47

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

Collection date (dd MMM yyyy)	28 JAN 2021
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Collection time (00:00 - 23:59)	10:07
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Collection Date and Time (derived)	28 JAN 2021 10:07
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US3672407

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

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:37:53

Generated On: 11 Aug 2021 23:01:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672407

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:37:53

Generated On: 11 Aug 2021 23:01:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3672407

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:37:53

Generated On: 11 Aug 2021 23:01:47

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

US3672407

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Apr 2021 18:37:32

Generated On: 11 Aug 2021 23:01:47

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

US3672407

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Apr 2021 15:34:44

Generated On: 11 Aug 2021 23:01:47

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 MAR 2021
Time of assessment (00:00-23:59)	09:57 (24 HR)
Vital Signs Date and Time (derived)	11 MAR 2021 09:57
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG



US3672407

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Apr 2021 15:34:44

Generated On: 11 Aug 2021 23:01:47

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 MAR 2021
Time of assessment (00:00-23:59)	10:46 (24 HR)
Vital Signs Date and Time (derived)	11 MAR 2021 10:46
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3672407

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 15:34:44

Generated On: 11 Aug 2021 23:01:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 MAR 2021

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

US3672407

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 16 Apr 2021 15:34:44

Generated On: 11 Aug 2021 23:01:47

Was the pregnancy test performed? Yes ☒  
No ☐

Date of test (dd MMM yyyy) 11 MAR 2021

Test performed Urine ☒  
Serum ☐

Result Positive ☐  
Negative ☒

Was FSH sample collected? Yes ☐  
No ☒

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

US3672407

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 16 Apr 2021 15:34:44

Generated On: 11 Aug 2021 23:01:47

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 11 MAR 2021

What was the treatment time? (00:00-23:59) 10:15 (24 HR)

Treatment Date and Time (derived) 11 MAR 2021 10:15

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

US3672407

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 15:34:44

Generated On: 11 Aug 2021 23:01:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672407

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 15:34:44

Generated On: 11 Aug 2021 23:01:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3672407

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 15:34:44

Generated On: 11 Aug 2021 23:01:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672407

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 15:34:44

Generated On: 11 Aug 2021 23:01:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 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



US3672407

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 15:34:44

Generated On: 11 Aug 2021 23:01:47

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) \_\_\_\_\_

US3672407

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 15:34:44

Generated On: 11 Aug 2021 23:01:47

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.*

US3672407

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 15:34:44

Generated On: 11 Aug 2021 23:01:47

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

06 APR 2021

Collection time (00:00-23:59)

10:02 (24 HR)

Collection date and time (derived)

06 APR 2021 10:02

US3672407

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 05 Mar 2021 18:37:52

Generated On: 11 Aug 2021 23:01:47

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3672407

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 05 Mar 2021 18:37:52

Generated On: 11 Aug 2021 23:01:47

AEID

Adverse event

PREMATURE VENTRICULAR  
CONTRACTIONS

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)

07 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)

24 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 (1)

Data signed: (b) (4) 05 Mar 2021 18:37:52

Generated On: 11 Aug 2021 23:01:47

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 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)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Mar 2021 18:37:53

Generated On: 11 Aug 2021 23:01:47

---

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

Yes ☒

No ☐

---

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

---

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Mar 2021 18:37:52

Generated On: 11 Aug 2021 23:01:47

Name of Medication BLISOVI FE 24

Prophylaxis Yes ☒  
No ☐

Indication CONTRACEPTION

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Mar 2021 18:37:52

Generated On: 11 Aug 2021 23:01:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Mar 2021 18:37:52

Generated On: 11 Aug 2021 23:01:47

Name of Medication ZOLOFT

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Mar 2021 18:37:52

Generated On: 11 Aug 2021 23:01:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Mar 2021 18:37:52

Generated On: 11 Aug 2021 23:01:47

Name of Medication	VITAMIN D
Prophylaxis	Yes <input checked="" type="radio"/> No <input type="radio"/>
Indication	HEALTH MAINTENANCE
Dose per administration	10000
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input checked="" type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Mar 2021 18:37:52

Generated On: 11 Aug 2021 23:01:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	25 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Mar 2021 18:37:52

Generated On: 11 Aug 2021 23:01:47

Name of Medication QUERCETINE

Prophylaxis Yes ☒  
No ☐

Indication HEALTH MANAGEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 05 Mar 2021 18:37:52

Generated On: 11 Aug 2021 23:01:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JUL 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	25 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Mar 2021 18:37:52

Generated On: 11 Aug 2021 23:01:47

Name of Medication VALTREX

Prophylaxis Yes ☐  
No ☒

Indication MHX: HERPES GENITALIS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 05 Mar 2021 18:37:52

Generated On: 11 Aug 2021 23:01:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 JUN 2014	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Mar 2021 18:37:52

Generated On: 11 Aug 2021 23:01:47

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 05 Mar 2021 18:37:52

Generated On: 11 Aug 2021 23:01:47

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		22 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3672407

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Mar 2021 18:37:53

Generated On: 11 Aug 2021 23:01:47

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3672407

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 05 Mar 2021 18:37:53

Generated On: 11 Aug 2021 23:01:47

---

Date of dosing discontinuation (dd MMM yyyy) 29 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#1

---

US3672407

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 23:01:47

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

US3672407 (Prod: Coastal Carolina Research Center)

**US3672407**

**Form: Participant Creation**

**Generated On: 11 Aug 2021 23:01:47**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Oct 2020 19:19:00
User entered 'US3672407'	RWS_ENDPOINT	03 Sep 2020 18:39:48
	ENDPOINT (b) (4)	



**US3672407**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:01:47**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:20:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 19:35:10

US3672407

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 23:01:47

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
User closed query "Per CDM: Please, complete Medical History, Physical Examination, Vital signs, Childbearing Potential, and Risk of Exposure form for screening visit per pages 15-16 of CCGs.' Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 12:10:16
Query "Per CDM: Please, complete Medical History, Physical Examination, Vital signs, Childbearing Potential, and Risk of Exposure form for screening visit per pages 15-16 of CCGs.' Thank you' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 14:32:42
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:20:21
User opened query "Per CDM: Please, complete Medical History, Physical Examination, Vital signs, Childbearing Potential, and Risk of Exposure form for screening visit per pages 15-16 of CCGs.' Thank you' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 07:49:59
User entered '03 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 18:39:49

US3672407

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 23:01:47

[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 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:20:21
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	03 Sep 2020 19:35:10

**US3672407**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:01:47**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered 'SCRN'	System	03 Sep 2020 19:35:10

US3672407

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:01:47

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:20:25
User entered (b) (6) 1979'	RWS_ENDPOINT	03 Sep 2020 18:39:50
	ENDPOINT (b) (4)	

**US3672407**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:01:47**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:20:25
User entered '41'	(b) (4), (b) (6)	03 Sep 2020 19:35:33

**US3672407**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:01:47**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered 'YEARS'	System	03 Sep 2020 19:35:33

**US3672407**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:01:47**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered '41'	System	03 Sep 2020 19:35:57



**US3672407**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:01:47**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:20:25
User entered 'Female (F)'	(b) (4), (b) (6)	03 Sep 2020 19:35:33

US3672407

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:01:47

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:20:25
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	03 Sep 2020 19:35:33

**US3672407**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:01:47**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:20:25
User entered 'I'	(b) (4), (b) (6)	03 Sep 2020 19:35:33

**US3672407**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:01:47**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:20:25
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 19:35:33

**US3672407**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:01:47**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:20:25
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 19:35:33

**US3672407**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:01:47**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:20:25
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 19:35:33

**US3672407**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:01:47**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:20:25
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 19:35:33

**US3672407**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:01:47**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:20:25
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 19:35:33



**US3672407**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:01:47**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:20:25
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 19:35:33

**US3672407**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:01:47**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:20:25
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 19:35:33

**US3672407**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:01:47**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:20:25
User entered '0'	(b) (4), (b) (6)	03 Sep 2020 19:35:33

**US3672407**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:01:47**

**Date of Informed Consent** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:20:30
User entered '3 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 19:35:57

**US3672407**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered 'Sep 2020'	System	03 Sep 2020 19:35:57

**US3672407**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered '2020'	System	03 Sep 2020 19:35:57

**US3672407**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:01:47**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:20:30
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	03 Sep 2020 19:35:57

**US3672407**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:20:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 19:35:57



**US3672407**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:20:30
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 19:35:57

**US3672407**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:01:47**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:20:30
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 19:35:57

**US3672407**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:01:47**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:20:30
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 19:35:57

**US3672407**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:01:47**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:20:30
User entered empty.	RWS_ENDPOINT	03 Sep 2020 18:39:49
	ENDPOINT (b) (4)	

**US3672407**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:01:47**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered 'I'	System	03 Sep 2020 19:36:13

**US3672407**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 19:19:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 19:36:13

US3672407

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 23:01:47

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
User closed query 'Please update MH, Vital signs, PE, Childbearing potential and Risk of exposure page. ' (Site from CRA).	(b) (4)	
	(b) (4), (b) (6)	19 Oct 2020 19:19:27
Query 'Please update MH, Vital signs, PE, Childbearing potential and Risk of exposure page. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 14:33:10
User opened query 'Please update MH, Vital signs, PE, Childbearing potential and Risk of exposure page. ' (Site from CRA).	(b) (4), (b) (6)	22 Sep 2020 15:22:42
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:20:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 19:36:19

US3672407

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:01:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 19:54:42
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 18:22:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 18:22:44
Data point term sent to Coder	System	22 Sep 2020 18:21:22
User entered 'depression'	(b) (4), (b) (6)	22 Sep 2020 18:21:05



**US3672407**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:54:42
User entered 'un UNK 2016'	(b) (4), (b) (6)	22 Sep 2020 18:21:05

**US3672407**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:54:42
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 18:21:05

**US3672407**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:54:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 18:21:05

**US3672407**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:01:47**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:54:42
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 18:21:05

**US3672407**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:54:42
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 18:21:05

US3672407

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:01:47

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered 'Jan 2016'	System	22 Sep 2020 18:21:05

**US3672407**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered '2016'	System	22 Sep 2020 18:21:05

**US3672407**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered empty.	System	22 Sep 2020 18:21:05



**US3672407**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered empty.	System	22 Sep 2020 18:21:05

US3672407

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:01:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergic reaction to antibiotics - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 20:13:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 20:13:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:54:42
Data point term sent to Coder	System	22 Sep 2020 18:21:22
User entered 'augmentin allergy- nausea'	(b) (4), (b) (6)	22 Sep 2020 18:21:20

**US3672407**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:54:42
User entered 'un UNK 1997'	(b) (4), (b) (6)	22 Sep 2020 18:21:20

**US3672407**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 23:01:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:54:42
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 18:21:20

**US3672407**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 23:01:47**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 19:54:42
		22 Sep 2020 18:21:20

**US3672407**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 23:01:47**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:54:42
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 18:21:20

**US3672407**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 23:01:47**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:54:42
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 18:21:20

**US3672407**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 23:01:47**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered 'Jan 1997'	System	22 Sep 2020 18:21:20



**US3672407**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 23:01:47**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered '1997'	System	22 Sep 2020 18:21:20

**US3672407**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 23:01:47**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered empty.	System	22 Sep 2020 18:21:20

**US3672407**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 23:01:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered empty.	System	22 Sep 2020 18:21:20

US3672407

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:01:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Ventricular arrhythmias and cardiac arrest, PT: Ventricular extrasystoles, LLT: Premature ventricular contractions - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 07:59:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 07:59:23
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:54:42
Data point term sent to Coder	System	22 Sep 2020 18:22:23
User entered 'pvc-premature ventricular contractions'	(b) (4), (b) (6)	22 Sep 2020 18:21:46

US3672407

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:01:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
User closed query 'Per source, this start date is UN UNK 2018. Please verify and update accordingly' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 16:00:27
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:00:23
Query 'Per source, this start date is UN UNK 2018. Please verify and update accordingly' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 16:24:30
DataPoint Un-verified.	(b) (4), (b) (6)	20 Oct 2020 16:24:24
User entered 'UN UNK 2018' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 16:24:24
User opened query 'Per source, this start date is UN UNK 2018. Please verify and update accordingly' (Site from CRA).	(b) (4), (b) (6)	19 Oct 2020 19:15:50
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:54:42
User entered 'un UNK 2020'	(b) (4), (b) (6)	22 Sep 2020 18:21:46

**US3672407**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 23:01:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:54:42
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 18:21:46

**US3672407**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 23:01:47**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 16:00:33
DataPoint Un-verified.	(b) (4), (b) (6)	20 Oct 2020 16:24:24
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 16:24:24
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:54:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 18:21:46

**US3672407**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 23:01:47**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 16:00:36
DataPoint Un-verified.	(b) (4), (b) (6)	20 Oct 2020 16:24:24
User entered 'un UNK 2018' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 16:24:24
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:54:42
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 18:21:46



**US3672407**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 23:01:47**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:54:42
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 18:21:46

**US3672407**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 23:01:47**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered 'Jan 2018'	System	20 Oct 2020 16:24:24
User entered 'Jan 2020'	System	22 Sep 2020 18:21:46

**US3672407**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 23:01:47**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered '2018'	System	20 Oct 2020 16:24:24
User entered '2020'	System	22 Sep 2020 18:21:46

**US3672407**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 23:01:47**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered 'Jan 2018'	System	20 Oct 2020 16:24:24
User entered empty.	System	22 Sep 2020 18:21:46

**US3672407**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 23:01:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered '2018'	System	20 Oct 2020 16:24:24
User entered empty.	System	22 Sep 2020 18:21:46

US3672407

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 23:01:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 19:12:43
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Genital herpes, LLT: Herpes genitalis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 13:55:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 13:55:30
Data point term sent to Coder	System	09 Oct 2020 13:54:46
User entered 'Herpes Genitalis'	(b) (4), (b) (6)	09 Oct 2020 13:53:47

**US3672407**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 19:12:43
User entered '17 Jun 2014'	(b) (4), (b) (6)	09 Oct 2020 13:53:47

**US3672407**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 23:01:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 19:12:43
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 13:53:47



**US3672407**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 23:01:47**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 19:12:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 13:53:47

**US3672407**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 23:01:47**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 19:12:43
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 13:53:47

**US3672407**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 23:01:47**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 19:12:43
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 13:53:47

**US3672407**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 23:01:47**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered 'Jun 2014'	System	09 Oct 2020 13:53:47

**US3672407**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 23:01:47**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered '2014'	System	09 Oct 2020 13:53:47

**US3672407**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 23:01:47**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered empty.	System	09 Oct 2020 13:53:47

**US3672407**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 23:01:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered empty.	System	09 Oct 2020 13:53:47

**US3672407**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 19:54:51
	(b) (4), (b) (6)	22 Sep 2020 18:22:45



**US3672407**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:54:51
User entered '03 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 18:22:45

**US3672407**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:54:51
User entered '14:50'	(b) (4), (b) (6)	22 Sep 2020 18:22:45

**US3672407**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered '03 Sep 2020 14:50'	System	22 Sep 2020 18:22:45

**US3672407**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:54:51
User entered '166' cm	(b) (4), (b) (6)	22 Sep 2020 18:22:45
DataPoint set to visible.	System	03 Sep 2020 19:36:13

**US3672407**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:54:51
User entered '88' kg	(b) (4), (b) (6)	22 Sep 2020 18:22:45
DataPoint set to visible.	System	03 Sep 2020 19:36:13

US3672407

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:47

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered '31.93497'	System	22 Sep 2020 18:22:45
DataPoint set to visible.	System	03 Sep 2020 19:36:13

US3672407

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:47

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered 'kg/m2'	System	22 Sep 2020 18:22:45
DataPoint set to visible.	System	03 Sep 2020 19:36:13

**US3672407**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:54:51
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Sep 2020 18:22:45



**US3672407**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:54:51
User entered 'Other (Other)'	(b) (4), (b) (6)	22 Sep 2020 18:22:45

**US3672407**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:54:51
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Sep 2020 18:22:45

**US3672407**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:54:51
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Sep 2020 18:22:45

**US3672407**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered 'bpm'	System	22 Sep 2020 18:22:45

**US3672407**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:54:51
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Sep 2020 18:22:45

US3672407

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered 'breaths/min'	System	22 Sep 2020 18:22:45

**US3672407**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:54:51
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Sep 2020 18:22:45

US3672407

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered 'mmHg'	System	22 Sep 2020 18:22:45



**US3672407**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:54:51
User entered missing code ND - Not Done.	(b) (4), (b) (6)	22 Sep 2020 18:22:45

**US3672407**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered 'mmHg'	System	22 Sep 2020 18:22:45

US3672407

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:47

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03

**US3672407**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03

**US3672407**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:01:47**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:54:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 18:22:51

**US3672407**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:54:56
User entered '03 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 18:22:51

**US3672407**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:55:00
User entered '03 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 18:23:13

**US3672407**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:55:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 18:23:13



**US3672407**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:55:00
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 18:23:13

**US3672407**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 19:55:00
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 18:23:13

**US3672407**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:55:00
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 18:23:13

**US3672407**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 23:01:47**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:55:00
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 18:23:13

**US3672407**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:55:00
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 18:23:13

**US3672407**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 23:01:47**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:55:00
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 18:23:13

**US3672407**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:01:47**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:55:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 18:23:24

**US3672407**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:55:03
User entered '03 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 18:23:24



**US3672407**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:01:47**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:55:03
User entered 'Urine (URINE)'	(b) (4), (b) (6)	22 Sep 2020 18:23:24

**US3672407**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:01:47**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:55:03
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	22 Sep 2020 18:23:24

**US3672407**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:01:47**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:55:03
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 18:23:24

**US3672407**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:01:47**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:55:03
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 18:23:24

**US3672407**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:01:47**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:55:03
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 18:23:24

**US3672407**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered empty.	System	22 Sep 2020 18:23:24

US3672407

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:01:47

[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 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:55:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 18:24:12

US3672407

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:01:47

**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 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:55:39
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 18:24:12



US3672407

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:01:47

**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 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:55:39
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 18:24:12

US3672407

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:01:47

**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 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:55:39
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 18:24:12

US3672407

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:01:47

[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 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:55:39
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 18:24:12

US3672407

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:01:47

[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 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:55:39
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 18:24:12

US3672407

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:01:47

**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 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:55:39
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 18:24:12

US3672407

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:01:47

**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 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:55:39
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 18:24:12

US3672407

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:01:47

[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 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 19:55:39
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 18:24:12

US3672407

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:01:47

**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 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:55:39
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 18:24:12



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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:01:47

**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 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:55:39
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 18:24:12

**US3672407**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 23:01:47**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:55:39
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 18:24:12

**US3672407**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 23:01:47**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:55:39
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 18:24:12

**US3672407**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 23:01:47**

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 18:24:12

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:55:39
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 18:24:12

US3672407

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:01:47

**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 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:55:39
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 18:24:12

US3672407

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:01:47

**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 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:55:39
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 18:24:12

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:01:47

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 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:55:39
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 18:24:12



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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:55:39
User entered 'I'	(b) (4), (b) (6)	22 Sep 2020 18:24:12

**US3672407**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 23:01:47**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
User entered 'I'	(b) (4), (b) (6)	22 Sep 2020 18:24:12

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:01:47

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:55:39
User entered 'Resident in a community with ongoing person to person transmission.'	(b) (4), (b) (6)	22 Sep 2020 18:24:12

**US3672407**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:01:47**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:23:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 19:36:28

**US3672407**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:23:54
User entered '3 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 19:36:28

US3672407

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 23:01:47

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:23:54
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	03 Sep 2020 19:36:28

**US3672407**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:01:47**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User entered 'VISIT1'	System	03 Sep 2020 19:36:28

US3672407

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
User closed query 'Per CDM: Please complete Vitals Signs - Dosing, Physical Examination ,Immunogenicity Assessment, Central Laboratory - Nasopharyngeal Swab , Continuing forms for V1D1 as per pages 15-16 of CCGs. Thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 10:06:17
Query 'Per CDM: Please complete Vitals Signs - Dosing, Physical Examination ,Immunogenicity Assessment, Central Laboratory - Nasopharyngeal Swab , Continuing forms for V1D1 as per pages 15-16 of CCGs. Thank you. ' answered with 'completed' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 18:24:28
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:23:57
User opened query 'Per CDM: Please complete Vitals Signs - Dosing, Physical Examination ,Immunogenicity Assessment, Central Laboratory - Nasopharyngeal Swab , Continuing forms for V1D1 as per pages 15-16 of CCGs. Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 07:50:35
User entered '03 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Sep 2020 19:00:07



US3672407

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:23:57
User entered '111292'	RWS_ENDPOINT	03 Sep 2020 19:00:07
	ENDPOINT (b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:23:57
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT	03 Sep 2020 19:00:07
	ENDPOINT (b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:01:47

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)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:23:57
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 19:36:37

US3672407

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:01:47

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)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:23:57
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 19:36:37

**US3672407**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:23:57
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 19:36:37

**US3672407**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:23:57
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 19:36:37

**US3672407**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 23:01:47**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:23:57
User entered 'No (N)'	(b) (4), (b) (6)	03 Sep 2020 19:36:37

**US3672407**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Oct 2020 19:19:41
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 18:24:39
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:16:08
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:16:07



**US3672407**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:01:47**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:24:21
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Sep 2020 15:55:59

US3672407

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:01:47

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:24:21
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Sep 2020 15:55:59

**US3672407**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:01:47**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:24:21
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Sep 2020 15:55:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:01:47

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:24:21
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Sep 2020 15:55:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	04 Sep 2020 15:55:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:24:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 15:55:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:24:21
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 15:59:28
User entered '03 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 15:59:28
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 15:55:59
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:55:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:24:21
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 15:59:28
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Sep 2020 15:59:28
User entered '14:50' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 15:59:28
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 15:55:59
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:55:59



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User entered '03 Sep 2020 14:50'	System	04 Sep 2020 15:59:28
User entered empty.	System	04 Sep 2020 15:55:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:24:21
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 15:59:28
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Sep 2020 15:59:28
User entered '98.1' F reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 15:59:28
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 15:55:59
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:55:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	22 Sep 2020 15:24:21
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 15:59:33
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Sep 2020 15:59:33
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 15:59:33
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 15:59:28
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:55:59

**US3672407**

**Folder: Visit 1 Day 1**

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

**Generated On: 11 Aug 2021 23:01:47**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:24:21
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:55:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:24:21
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 15:59:28
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Sep 2020 15:59:28
User entered '61' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 15:59:28
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 15:55:59
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:55:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User entered 'bpm'	System	04 Sep 2020 15:59:28
User entered empty.	System	04 Sep 2020 15:55:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	22 Sep 2020 15:24:21
User closed query 'Data is required. Please provide.'	System	04 Sep 2020 15:59:28
(Site from System).		
Query 'Data is required. Please provide.' answered by System		04 Sep 2020 15:59:28
data change (Site from System).		
User entered '16' reason for change: Data Entry	(b) (4), (b) (6)	04 Sep 2020 15:59:28
Error		
User opened query 'Data is required. Please provide.'	System	04 Sep 2020 15:55:59
(Site from System).		
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:55:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User entered 'breaths/min'	System	04 Sep 2020 15:59:28
User entered empty.	System	04 Sep 2020 15:55:59



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:24:21
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 15:59:28
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Sep 2020 15:59:28
User entered '118' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 15:59:28
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 15:55:59
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:55:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User entered 'mmHg'	System	04 Sep 2020 15:59:28
User entered empty.	System	04 Sep 2020 15:55:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:24:21
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 15:59:28
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Sep 2020 15:59:28
User entered '71' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 15:59:28
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 15:55:59
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:55:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User entered 'mmHg'	System	04 Sep 2020 15:59:28
User entered empty.	System	04 Sep 2020 15:55:59

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:01:47**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:24:21
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Sep 2020 15:55:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:01:47

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:24:21
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Sep 2020 15:55:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	04 Sep 2020 15:55:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:24:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 15:55:59



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Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:24:21
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 16:00:33
User entered '03 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 16:00:33
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 15:55:59
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:55:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:24:21
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 16:00:33
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Sep 2020 16:00:33
User entered '15:52' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 16:00:33
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 15:55:59
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:55:59

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Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User entered '03 Sep 2020 15:52'	System	04 Sep 2020 16:00:33
User entered empty.	System	04 Sep 2020 15:55:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:24:21
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 16:00:33
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Sep 2020 16:00:33
User entered '98.5' F reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 16:00:33
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 15:55:59
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:55:59

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

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[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:24:21
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 16:00:33
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:55:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:24:21
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:55:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:24:21
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 16:00:33
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Sep 2020 16:00:33
User entered '56' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 16:00:33
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 15:55:59
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:55:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User entered 'bpm'	System	04 Sep 2020 16:00:33
User entered empty.	System	04 Sep 2020 15:55:59



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:24:21
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 16:00:33
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Sep 2020 16:00:33
User entered '15' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 16:00:33
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 15:55:59
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:55:59

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Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User entered 'breaths/min'	System	04 Sep 2020 16:00:33
User entered empty.	System	04 Sep 2020 15:55:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:24:21
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 16:00:33
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Sep 2020 16:00:33
User entered '107' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 16:00:33
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 15:55:59
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:55:59

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Form: Vital Signs - Dosing (2)

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[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User entered 'mmHg'	System	04 Sep 2020 16:00:33
User entered empty.	System	04 Sep 2020 15:55:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:24:21
User closed query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 16:00:33
Query 'Data is required. Please provide.' answered by System data change (Site from System).		04 Sep 2020 16:00:33
User entered '64' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 16:00:33
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Sep 2020 15:55:59
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:55:59

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Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User entered 'mmHg'	System	04 Sep 2020 16:00:33
User entered empty.	System	04 Sep 2020 15:55:59

US3672407

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 23:01:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:24:25
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 16:01:22

**US3672407**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:24:25
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:01:22



US3672407

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:47

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:04:33
User closed query 'Per CDM: Please note if screening and VID1 date is on the same day, kindly complete the Pregnancy Test form on the screening folder and change the Pregnancy Test performed on VID1 to "NO". Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 12:19:06
Query 'Per CDM: Please note if screening and VID1 date is on the same day, kindly complete the Pregnancy Test form on the screening folder and change the Pregnancy Test performed on VID1 to "NO". Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 14:32:07
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 14:32:00
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 14:32:00
User opened query 'Per CDM: Please note if screening and VID1 date is on the same day, kindly complete the Pregnancy Test form on the screening folder and change the Pregnancy Test performed on VID1 to "NO". Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 12:33:11
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:55:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 18:24:51

US3672407

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:47

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:04:34
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 14:32:00
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 14:32:00
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:55:53
User entered '03 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 18:24:51

US3672407

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:47

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:04:50
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 14:32:00
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 14:32:00
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:55:53
User entered 'Urine (URINE)'	(b) (4), (b) (6)	22 Sep 2020 18:24:51

**US3672407**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:01:47**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:04:50
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 14:32:00
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 14:32:00
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:55:53
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	22 Sep 2020 18:24:51

US3672407

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:47

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:04:50
User closed query 'Per CDM: Please consider entering "No" for this field as screening and VID1 have occurred on the same day.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 06:05:17
Query 'Per CDM: Please consider entering "No" for this field as screening and VID1 have occurred on the same day.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 21:55:34
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 21:55:32
User opened query 'Per CDM: Please consider entering "No" for this field as screening and VID1 have occurred on the same day.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 12:35:43
Query 'Per CDM: As per the CCG Guidelines Page number 24, FSH sample collected: Yes OR No should be recorded, Kindly update accordingly.' canceled (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 12:35:19
User opened query 'Per CDM: As per the CCG Guidelines Page number 24, FSH sample collected: Yes OR No should be recorded, Kindly update accordingly.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 12:11:27
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 14:32:00
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 14:32:00
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:55:53
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 18:24:51

**US3672407**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:01:47**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 19:55:53
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 18:24:51

**US3672407**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:01:47**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 19:55:53
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 18:24:51

**US3672407**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User entered empty.	System	22 Sep 2020 18:24:51



US3672407

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:01:47

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:24:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 19:37:35

**US3672407**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:01:47**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:24:40
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 19:37:35

US3672407

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:24:40
User entered empty.	(b) (4), (b) (6)	03 Sep 2020 19:37:35

**US3672407**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:01:47**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 19:37:35

US3672407

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:01:47

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:24:40
User entered '3 Sep 2020'	(b) (4), (b) (6)	03 Sep 2020 19:37:35

**US3672407**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:24:40
User entered '15:21'	(b) (4), (b) (6)	03 Sep 2020 19:37:35

**US3672407**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User entered '3 Sep 2020 15:21'	System	03 Sep 2020 19:37:35

US3672407

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:24:40
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	03 Sep 2020 19:37:35



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:24:40
User entered 'ONCE'	System	03 Sep 2020 19:37:35

US3672407

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:01:47

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 19:37:35

**US3672407**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:01:47**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:24:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 16:02:19

US3672407

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:01:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:24:51
User entered '03 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 16:02:19

**US3672407**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:24:51
User entered '14:58'	(b) (4), (b) (6)	04 Sep 2020 16:02:19

**US3672407**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User entered '03 Sep 2020 14:58'	System	04 Sep 2020 16:02:19

**US3672407**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 11 Aug 2021 23:01:47**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:24:58
User entered '03 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 16:02:32

**US3672407**

**Folder: Visit 1 Day 1**

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

**Generated On: 11 Aug 2021 23:01:47**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	04 Sep 2020 16:02:32



US3672407

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:01:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:24:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 16:02:32

US3672407

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:01:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:24:58
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	04 Sep 2020 16:02:43
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	04 Sep 2020 16:02:43
User entered '14:38' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 16:02:43
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	04 Sep 2020 16:02:32
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:02:32

**US3672407**

**Folder: Visit 1 Day 1**

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

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User entered '03 Sep 2020 14:38'	System	04 Sep 2020 16:02:43
User entered empty.	System	04 Sep 2020 16:02:32

**US3672407**

**Folder: Visit 1 Day 1**

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

**Generated On: 11 Aug 2021 23:01:47**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	04 Sep 2020 16:02:32

**US3672407**

**Folder: Visit 1 Day 1**

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

**Generated On: 11 Aug 2021 23:01:47**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:24:58
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 16:02:32

**US3672407**

**Folder: Visit 1 Day 1**

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

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:24:58
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:02:32

**US3672407**

**Folder: Visit 1 Day 1**

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

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User entered empty.	System	04 Sep 2020 16:02:32

US3672407

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:25:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 16:02:51



**US3672407**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:01:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User entered 'I'	System	04 Sep 2020 16:02:51

US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
Data entry locked.	System	03 Sep 2020 19:37:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 19:37:35

US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 23:01:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-03T15:52:36', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'cc5492f9-d9d6-4413-b1fa-9d3b86ec3461'	System	03 Sep 2020 19:53:01
User entered 'Yes (Y)'	System	03 Sep 2020 19:53:01

US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 23:01:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-03T15:52:47', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'cc5492f9-d9d6-4413-b1fa-9d3b86ec3461'	System	03 Sep 2020 19:53:01
User entered '98.5'	System	03 Sep 2020 19:53:01

US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-03T15:52:51', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'cc5492f9-d9d6-4413-b1fa-9d3b86ec3461'	System	03 Sep 2020 19:53:01
User entered 'No (N)'	System	03 Sep 2020 19:53:01

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-03T15:52:59', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'cc5492f9-d9d6-4413-b1fa-9d3b86ec3461'	System	03 Sep 2020 19:53:01
User entered '03 Sep 2020 15:52'	System	03 Sep 2020 19:53:01

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '03 Sep 2020 15:41'	System	03 Sep 2020 19:37:35

US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 23:01:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '03 Sep 2020 18:11'	System	03 Sep 2020 19:37:35



US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
Data entry locked.	System	03 Sep 2020 19:37:35
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 19:37:35

US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 23:01:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-03T19:07:21', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '3b40077b-1bdf-4fbc-8f40-23e425b4dda1'	System	03 Sep 2020 23:07:37
User entered 'Yes (Y)'	System	03 Sep 2020 23:07:37

US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 23:01:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-03T19:07:27', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '3b40077b-1bdf-4fbc-8f40-23e425b4dda1'	System	03 Sep 2020 23:07:37
User entered '98.5'	System	03 Sep 2020 23:07:37

US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-03T19:07:32', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '3b40077b-1bdf-4fbc-8f40-23e425b4dda1'	System	03 Sep 2020 23:07:37
User entered 'No (N)'	System	03 Sep 2020 23:07:37

**US3672407**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 23:01:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-03T19:07:36', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '3b40077b-1bdf-4fbc-8f40-23e425b4dda1'	System	03 Sep 2020 23:07:37
User entered '03 Sep 2020 19:07'	System	03 Sep 2020 23:07:37

US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 23:01:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '03 Sep 2020 19:06'	System	03 Sep 2020 19:37:35

**US3672407**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 23:01:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 19:37:35

US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
Data entry locked.	System	03 Sep 2020 19:37:35
User entered 'Day 2'	System	03 Sep 2020 19:37:35



US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 23:01:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-04T13:09:02', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '064ab9a8-5921-4c4d-9430-52862aac29a8'	System	04 Sep 2020 17:09:26
User entered 'Yes (Y)'	System	04 Sep 2020 17:09:26

US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 23:01:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-04T13:09:13', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '064ab9a8-5921-4c4d-9430-52862aac29a8'	System	04 Sep 2020 17:09:26
User entered '98.6'	System	04 Sep 2020 17:09:26

US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-04T13:09:17', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '064ab9a8-5921-4c4d-9430-52862aac29a8'	System	04 Sep 2020 17:09:26
User entered 'No (N)'	System	04 Sep 2020 17:09:26

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-04T13:09:20', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '064ab9a8-5921-4c4d-9430-52862aac29a8'	System	04 Sep 2020 17:09:26
User entered '04 Sep 2020 13:09'	System	04 Sep 2020 17:09:26

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 19:37:35

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 19:37:35

US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
Data entry locked.	System	03 Sep 2020 19:37:35
User entered 'Day 3'	System	03 Sep 2020 19:37:35

US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 23:01:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-05T12:01:26', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '24ecf90f-49bc-42ef-8818-e2a7802f82ba'	System	05 Sep 2020 16:02:44
User entered 'Yes (Y)'	System	05 Sep 2020 16:02:44



US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 23:01:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-05T12:01:39', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '24ecf90f-49bc-42ef-8818-e2a7802f82ba'	System	05 Sep 2020 16:02:44
User entered '97.8'	System	05 Sep 2020 16:02:44

US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-05T12:01:42', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '24ecf90f-49bc-42ef-8818-e2a7802f82ba'	System	05 Sep 2020 16:02:44
User entered 'No (N)'	System	05 Sep 2020 16:02:44

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-05T12:01:46', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '24ecf90f-49bc-42ef-8818-e2a7802f82ba'	System	05 Sep 2020 16:02:44
User entered '05 Sep 2020 12:01'	System	05 Sep 2020 16:02:44

US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 23:01:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 19:37:35

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 19:37:35

US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
Data entry locked.	System	03 Sep 2020 19:37:35
User entered 'Day 4'	System	03 Sep 2020 19:37:35

US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 23:01:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-06T18:12:55', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '14ffd267-9553-4e81-82f5-261f51ab8d42'	System	06 Sep 2020 22:13:13
User entered 'Yes (Y)'	System	06 Sep 2020 22:13:13

US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 23:01:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-06T18:13:02', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '14ffd267-9553-4e81-82f5-261f51ab8d42'	System	06 Sep 2020 22:13:13
User entered '98.8'	System	06 Sep 2020 22:13:13



US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-06T18:13:06', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '14ffd267-9553-4e81-82f5-261f51ab8d42'	System	06 Sep 2020 22:13:13
User entered 'No (N)'	System	06 Sep 2020 22:13:13

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-06T18:13:10', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '14ffd267-9553-4e81-82f5-261f51ab8d42'	System	06 Sep 2020 22:13:13
User entered '06 Sep 2020 18:13'	System	06 Sep 2020 22:13:13

US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 23:01:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 19:37:35

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 19:37:35

US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
Data entry locked.	System	03 Sep 2020 19:37:35
User entered 'Day 5'	System	03 Sep 2020 19:37:35

US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 23:01:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-07T18:55:50', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '734fc900-4b5a-4a1b-b22f-e32b38b4e895'	System	07 Sep 2020 22:56:06
User entered 'Yes (Y)'	System	07 Sep 2020 22:56:06

US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 23:01:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-07T18:55:56', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '734fc900-4b5a-4a1b-b22f-e32b38b4e895'	System	07 Sep 2020 22:56:06
User entered '98.8'	System	07 Sep 2020 22:56:06

US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-07T18:56:00', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '734fc900-4b5a-4a1b-b22f-e32b38b4e895'	System	07 Sep 2020 22:56:06
User entered 'No (N)'	System	07 Sep 2020 22:56:06



**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-07T18:56:03', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '734fc900-4b5a-4a1b-b22f-e32b38b4e895'	System	07 Sep 2020 22:56:06
User entered '07 Sep 2020 18:56'	System	07 Sep 2020 22:56:06

US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 23:01:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 19:37:35

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 19:37:35

US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
Data entry locked.	System	03 Sep 2020 19:37:35
User entered 'Day 6'	System	03 Sep 2020 19:37:35

US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 23:01:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-09T10:42:54', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '344d35b1-111e-42a5-a9a9-11dfb1fcf347'	System	09 Sep 2020 14:43:12
User entered 'Yes (Y)'	System	09 Sep 2020 14:43:12

US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 23:01:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-09T10:43:02', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '344d35b1-111e-42a5-a9a9-11dfb1fcf347'	System	09 Sep 2020 14:43:12
User entered '97.8'	System	09 Sep 2020 14:43:12

US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-09T10:43:05', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '344d35b1-111e-42a5-a9a9-11dfb1fcf347'	System	09 Sep 2020 14:43:12
User entered 'No (N)'	System	09 Sep 2020 14:43:12

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-09T10:43:08', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '344d35b1-111e-42a5-a9a9-11dfb1fcf347'	System	09 Sep 2020 14:43:12
User entered '09 Sep 2020 10:43'	System	09 Sep 2020 14:43:12



US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 23:01:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 19:37:35

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 19:37:35

US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
Data entry locked.	System	03 Sep 2020 19:37:35
User entered 'Day 7'	System	03 Sep 2020 19:37:35

US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 23:01:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-09T20:11:45', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '7558f0e8-7134-451c-9cf7-cec2ed268456'	System	10 Sep 2020 00:12:05
User entered 'Yes (Y)'	System	10 Sep 2020 00:12:05

US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 23:01:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-09T20:11:52', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '7558f0e8-7134-451c-9cf7-cec2ed268456'	System	10 Sep 2020 00:12:05
User entered '98.6'	System	10 Sep 2020 00:12:05

US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-09T20:11:56', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '7558f0e8-7134-451c-9cf7-cec2ed268456'	System	10 Sep 2020 00:12:05
User entered 'No (N)'	System	10 Sep 2020 00:12:05

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-09T20:11:59', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '7558f0e8-7134-451c-9cf7-cec2ed268456'	System	10 Sep 2020 00:12:05
User entered '09 Sep 2020 20:11'	System	10 Sep 2020 00:12:05

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 19:37:35



US3672407

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 23:01:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 19:37:35

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
Data entry locked.	System	03 Sep 2020 19:37:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 19:37:35

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:01:47

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 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-03T15:53:12', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '3915f2f4-a522-4864-afb6-d7b7a2f46762'	System	03 Sep 2020 19:53:40
User entered 'None (1)'	System	03 Sep 2020 19:53:40

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-03T15:53:21', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '3915f2f4-a522-4864-afb6-d7b7a2f46762'	System	03 Sep 2020 19:53:40
User entered 'No (N)'	System	03 Sep 2020 19:53:40

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-03T15:53:27', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '3915f2f4-a522-4864-afb6-d7b7a2f46762'	System	03 Sep 2020 19:53:40
User entered 'No (N)'	System	03 Sep 2020 19:53:40

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:01:47

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 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-03T15:53:33', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '3915f2f4-a522-4864-afb6-d7b7a2f46762'	System	03 Sep 2020 19:53:40
User entered 'None (1)'	System	03 Sep 2020 19:53:40

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-03T15:53:37', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '3915f2f4-a522-4864-afb6-d7b7a2f46762'	System	03 Sep 2020 19:53:40
User entered '03 Sep 2020 15:53'	System	03 Sep 2020 19:53:40

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '03 Sep 2020 15:41'	System	03 Sep 2020 19:37:35



**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '03 Sep 2020 18:11'	System	03 Sep 2020 19:37:35

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
Data entry locked.	System	03 Sep 2020 19:37:35
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 19:37:35

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:01:47

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 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-03T19:07:40', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '73c2ad4f-6235-4389-9303-22310c0619c2'	System	03 Sep 2020 23:07:54
User entered 'None (1)'	System	03 Sep 2020 23:07:54

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:01:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-03T19:07:42', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '73c2ad4f-6235-4389-9303-22310c0619c2'	System	03 Sep 2020 23:07:54
User entered 'No (N)'	System	03 Sep 2020 23:07:54

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-03T19:07:45', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '73c2ad4f-6235-4389-9303-22310c0619c2'	System	03 Sep 2020 23:07:54
User entered 'No (N)'	System	03 Sep 2020 23:07:54

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:01:47

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 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-03T19:07:48', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '73c2ad4f-6235-4389-9303-22310c0619c2'	System	03 Sep 2020 23:07:54
User entered 'None (1)'	System	03 Sep 2020 23:07:54

**US3672407**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 23:01:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-03T19:07:51', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '73c2ad4f-6235-4389-9303-22310c0619c2'	System	03 Sep 2020 23:07:54
User entered '03 Sep 2020 19:07'	System	03 Sep 2020 23:07:54

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:01:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '03 Sep 2020 19:06'	System	03 Sep 2020 19:37:35



**US3672407**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 23:01:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 19:37:35

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
Data entry locked.	System	03 Sep 2020 19:37:35
User entered 'Day 2'	System	03 Sep 2020 19:37:35

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:01:47

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 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-04T13:09:27', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'bb0cdd96-85ba-4219-957e-ac4b5b066140'	System	04 Sep 2020 17:09:44
User entered 'None (1)'	System	04 Sep 2020 17:09:44

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-04T13:09:30', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'bb0cdd96-85ba-4219-957e-ac4b5b066140'	System	04 Sep 2020 17:09:44
User entered 'No (N)'	System	04 Sep 2020 17:09:44

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-04T13:09:33', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'bb0cdd96-85ba-4219-957e-ac4b5b066140'	System	04 Sep 2020 17:09:44
User entered 'No (N)'	System	04 Sep 2020 17:09:44

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:01:47

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 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-04T13:09:36', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'bb0cdd96-85ba-4219-957e-ac4b5b066140'	System	04 Sep 2020 17:09:44
User entered 'None (1)'	System	04 Sep 2020 17:09:44

**US3672407**

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

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 23:01:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-04T13:09:40', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'bb0cdd96-85ba-4219-957e-ac4b5b066140'	System	04 Sep 2020 17:09:44
User entered '04 Sep 2020 13:09'	System	04 Sep 2020 17:09:44

**US3672407**

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

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 23:01:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 19:37:35



**US3672407**

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

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 23:01:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 19:37:35

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
Data entry locked.	System	03 Sep 2020 19:37:35
User entered 'Day 3'	System	03 Sep 2020 19:37:35

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:01:47

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 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-05T12:01:50', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '28117def-038b-46cc-acfd-c815045b11b6'	System	05 Sep 2020 16:03:08
User entered 'None (1)'	System	05 Sep 2020 16:03:08

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:01:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-05T12:01:53', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '28117def-038b-46cc-acfd-c815045b11b6'	System	05 Sep 2020 16:03:08
User entered 'No (N)'	System	05 Sep 2020 16:03:08

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-05T12:01:55', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '28117def-038b-46cc-acfd-c815045b11b6'	System	05 Sep 2020 16:03:08
User entered 'No (N)'	System	05 Sep 2020 16:03:08

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:01:47

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 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-05T12:01:58', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '28117def-038b-46cc-acfd-c815045b11b6'	System	05 Sep 2020 16:03:08
User entered 'None (1)'	System	05 Sep 2020 16:03:08

**US3672407**

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

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 23:01:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-05T12:02:05', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '28117def-038b-46cc-acfd-c815045b11b6'	System	05 Sep 2020 16:03:08
User entered '05 Sep 2020 12:02'	System	05 Sep 2020 16:03:08

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:01:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 19:37:35



**US3672407**

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

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 23:01:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 19:37:35

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
Data entry locked.	System	03 Sep 2020 19:37:35
User entered 'Day 4'	System	03 Sep 2020 19:37:35

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:01:47

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 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-06T18:13:14', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '5f67cac2-86ad-4f88-b56c-41604ef759a3'	System	06 Sep 2020 22:13:37
User entered 'None (1)'	System	06 Sep 2020 22:13:37

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-06T18:13:18', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '5f67cac2-86ad-4f88-b56c-41604ef759a3'	System	06 Sep 2020 22:13:37
User entered 'No (N)'	System	06 Sep 2020 22:13:37

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-06T18:13:21', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '5f67cac2-86ad-4f88-b56c-41604ef759a3'	System	06 Sep 2020 22:13:37
User entered 'No (N)'	System	06 Sep 2020 22:13:37

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:01:47

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 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-06T18:13:31', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '5f67cac2-86ad-4f88-b56c-41604ef759a3'	System	06 Sep 2020 22:13:37
User entered 'None (1)'	System	06 Sep 2020 22:13:37

**US3672407**

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

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 23:01:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-06T18:13:34', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '5f67cac2-86ad-4f88-b56c-41604ef759a3'	System	06 Sep 2020 22:13:37
User entered '06 Sep 2020 18:13'	System	06 Sep 2020 22:13:37

**US3672407**

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

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 23:01:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 19:37:35



**US3672407**

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

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 23:01:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 19:37:35

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
Data entry locked.	System	03 Sep 2020 19:37:35
User entered 'Day 5'	System	03 Sep 2020 19:37:35

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:01:47

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 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-07T18:56:08', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'f82c1f60-e9e8-442f-8f88-25cff0467b76'	System	07 Sep 2020 22:56:23
User entered 'None (1)'	System	07 Sep 2020 22:56:23

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-07T18:56:11', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'f82c1f60-e9e8-442f-8f88-25cff0467b76'	System	07 Sep 2020 22:56:23
User entered 'No (N)'	System	07 Sep 2020 22:56:23

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-07T18:56:13', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'f82c1f60-e9e8-442f-8f88-25cff0467b76'	System	07 Sep 2020 22:56:23
User entered 'No (N)'	System	07 Sep 2020 22:56:23

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:01:47

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 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-07T18:56:16', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'f82c1f60-e9e8-442f-8f88-25cff0467b76'	System	07 Sep 2020 22:56:23
User entered 'None (1)'	System	07 Sep 2020 22:56:23

**US3672407**

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

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 23:01:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-07T18:56:19', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'f82c1f60-e9e8-442f-8f88-25cff0467b76'	System	07 Sep 2020 22:56:23
User entered '07 Sep 2020 18:56'	System	07 Sep 2020 22:56:23

**US3672407**

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

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 23:01:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 19:37:35



**US3672407**

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

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 23:01:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 19:37:35

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
Data entry locked.	System	03 Sep 2020 19:37:35
User entered 'Day 6'	System	03 Sep 2020 19:37:35

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:01:47

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 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-09T10:43:12', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '2751434e-c24c-4b4b-a05d-9ac6071c64c5'	System	09 Sep 2020 14:43:25
User entered 'None (1)'	System	09 Sep 2020 14:43:25

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:01:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-09T10:43:14', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '2751434e-c24c-4b4b-a05d-9ac6071c64c5'	System	09 Sep 2020 14:43:25
User entered 'No (N)'	System	09 Sep 2020 14:43:25

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-09T10:43:16', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '2751434e-c24c-4b4b-a05d-9ac6071c64c5'	System	09 Sep 2020 14:43:25
User entered 'No (N)'	System	09 Sep 2020 14:43:25

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:01:47

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 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-09T10:43:18', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '2751434e-c24c-4b4b-a05d-9ac6071c64c5'	System	09 Sep 2020 14:43:25
User entered 'None (1)'	System	09 Sep 2020 14:43:25

**US3672407**

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

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 23:01:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-09T10:43:21', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '2751434e-c24c-4b4b-a05d-9ac6071c64c5'	System	09 Sep 2020 14:43:25
User entered '09 Sep 2020 10:43'	System	09 Sep 2020 14:43:25

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:01:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 19:37:35



**US3672407**

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

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 23:01:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 19:37:35

**US3672407**

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

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
Data entry locked.	System	03 Sep 2020 19:37:35
User entered 'Day 7'	System	03 Sep 2020 19:37:35

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:01:47

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 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-09T20:12:07', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '2deeb52a-3d15-4152-b8d5-746b05396f5a'	System	10 Sep 2020 00:12:20
User entered 'None (1)'	System	10 Sep 2020 00:12:20

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:01:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-09T20:12:10', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '2deeb52a-3d15-4152-b8d5-746b05396f5a'	System	10 Sep 2020 00:12:20
User entered 'No (N)'	System	10 Sep 2020 00:12:20

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-09T20:12:12', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '2deeb52a-3d15-4152-b8d5-746b05396f5a'	System	10 Sep 2020 00:12:20
User entered 'No (N)'	System	10 Sep 2020 00:12:20

US3672407

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:01:47

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 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-09T20:12:14', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '2deeb52a-3d15-4152-b8d5-746b05396f5a'	System	10 Sep 2020 00:12:20
User entered 'None (1)'	System	10 Sep 2020 00:12:20

**US3672407**

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

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 23:01:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-09T20:12:16', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '2deeb52a-3d15-4152-b8d5-746b05396f5a'	System	10 Sep 2020 00:12:20
User entered '09 Sep 2020 20:12'	System	10 Sep 2020 00:12:20

**US3672407**

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

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 23:01:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 19:37:35



**US3672407**

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

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 23:01:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 19:37:35

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
Data entry locked.	System	03 Sep 2020 19:37:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Sep 2020 19:37:35

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:01:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-03T15:53:42', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'e13b4888-9da4-4740-b82a-feb30ac3e486'	System	03 Sep 2020 19:54:04
User entered 'None (0)'	System	03 Sep 2020 19:54:04

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:01:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-03T15:53:44', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'e13b4888-9da4-4740-b82a-feb30ac3e486'	System	03 Sep 2020 19:54:04
User entered 'None (0)'	System	03 Sep 2020 19:54:04

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:01:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-03T15:53:47', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'e13b4888-9da4-4740-b82a-feb30ac3e486'	System	03 Sep 2020 19:54:04
User entered 'None (0)'	System	03 Sep 2020 19:54:04

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:01:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-03T15:53:50', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'e13b4888-9da4-4740-b82a-feb30ac3e486'	System	03 Sep 2020 19:54:04
User entered 'None (0)'	System	03 Sep 2020 19:54:04

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-03T15:53:52', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'e13b4888-9da4-4740-b82a-feb30ac3e486'	System	03 Sep 2020 19:54:04
User entered 'None (0)'	System	03 Sep 2020 19:54:04

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:01:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-03T15:53:54', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'e13b4888-9da4-4740-b82a-feb30ac3e486'	System	03 Sep 2020 19:54:04
User entered 'None (0)'	System	03 Sep 2020 19:54:04



US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:01:47

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 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-03T15:53:58', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'e13b4888-9da4-4740-b82a-feb30ac3e486'	System	03 Sep 2020 19:54:04
User entered 'No (N)'	System	03 Sep 2020 19:54:04

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-03T15:54:02', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'e13b4888-9da4-4740-b82a-feb30ac3e486'	System	03 Sep 2020 19:54:04
User entered '03 Sep 2020 15:54'	System	03 Sep 2020 19:54:04

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '03 Sep 2020 15:41'	System	03 Sep 2020 19:37:35

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '03 Sep 2020 18:11'	System	03 Sep 2020 19:37:35

**US3672407**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
Data entry locked.	System	03 Sep 2020 19:37:35
User entered 'Day 1, after vaccination (at home)'	System	03 Sep 2020 19:37:35

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:01:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-03T19:07:55', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '1852a8ec-52a7-4495-a569-e0f996c0f90c'	System	03 Sep 2020 23:08:11
User entered 'None (0)'	System	03 Sep 2020 23:08:11

**US3672407**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:01:47**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-03T19:07:57', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '1852a8ec-52a7-4495-a569-e0f996c0f90c'	System	03 Sep 2020 23:08:11
User entered 'None (0)'	System	03 Sep 2020 23:08:11

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:01:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-03T19:07:59', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '1852a8ec-52a7-4495-a569-e0f996c0f90c'	System	03 Sep 2020 23:08:11
User entered 'None (0)'	System	03 Sep 2020 23:08:11



US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:01:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-03T19:08:01', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '1852a8ec-52a7-4495-a569-e0f996c0f90c'	System	03 Sep 2020 23:08:11
User entered 'None (0)'	System	03 Sep 2020 23:08:11

**US3672407**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:01:47**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-03T19:08:02', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '1852a8ec-52a7-4495-a569-e0f996c0f90c'	System	03 Sep 2020 23:08:11
User entered 'None (0)'	System	03 Sep 2020 23:08:11

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:01:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-03T19:08:04', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '1852a8ec-52a7-4495-a569-e0f996c0f90c'	System	03 Sep 2020 23:08:11
User entered 'None (0)'	System	03 Sep 2020 23:08:11

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:01:47

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 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-03T19:08:07', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '1852a8ec-52a7-4495-a569-e0f996c0f90c'	System	03 Sep 2020 23:08:11
User entered 'No (N)'	System	03 Sep 2020 23:08:11

**US3672407**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:01:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-03T19:08:10', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '1852a8ec-52a7-4495-a569-e0f996c0f90c'	System	03 Sep 2020 23:08:11
User entered '03 Sep 2020 19:08'	System	03 Sep 2020 23:08:11

**US3672407**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:01:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '03 Sep 2020 19:06'	System	03 Sep 2020 19:37:35

**US3672407**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:01:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '04 Sep 2020 11:59'	System	03 Sep 2020 19:37:35

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
Data entry locked.	System	03 Sep 2020 19:37:35
User entered 'Day 2'	System	03 Sep 2020 19:37:35



**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-04T13:09:46', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'b200dd4b-8608-4a92-8747-9f8dcbe9f3ed'	System	04 Sep 2020 17:10:05
User entered 'None (0)'	System	04 Sep 2020 17:10:05

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-04T13:09:48', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'b200dd4b-8608-4a92-8747-9f8dcbe9f3ed'	System	04 Sep 2020 17:10:05
User entered 'None (0)'	System	04 Sep 2020 17:10:05

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 23:01:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-04T13:09:51', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'b200dd4b-8608-4a92-8747-9f8dcbe9f3ed'	System	04 Sep 2020 17:10:05
User entered 'None (0)'	System	04 Sep 2020 17:10:05

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 23:01:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-04T13:09:53', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'b200dd4b-8608-4a92-8747-9f8dcbe9f3ed'	System	04 Sep 2020 17:10:05
User entered 'None (0)'	System	04 Sep 2020 17:10:05

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-04T13:09:55', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'b200dd4b-8608-4a92-8747-9f8dcbe9f3ed'	System	04 Sep 2020 17:10:05
User entered 'None (0)'	System	04 Sep 2020 17:10:05

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-04T13:09:58', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'b200dd4b-8608-4a92-8747-9f8dcbe9f3ed'	System	04 Sep 2020 17:10:05
User entered 'None (0)'	System	04 Sep 2020 17:10:05

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 23:01:47

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 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-04T13:10:01', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'b200dd4b-8608-4a92-8747-9f8dcbe9f3ed'	System	04 Sep 2020 17:10:05
User entered 'No (N)'	System	04 Sep 2020 17:10:05

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-04T13:10:03', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'b200dd4b-8608-4a92-8747-9f8dcbe9f3ed'	System	04 Sep 2020 17:10:05
User entered '04 Sep 2020 13:10'	System	04 Sep 2020 17:10:05



**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 19:37:35

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 19:37:35

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
Data entry locked.	System	03 Sep 2020 19:37:35
User entered 'Day 3'	System	03 Sep 2020 19:37:35

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 23:01:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-05T12:02:09', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '6ccaf805-d1aa-4c2c-bd0b-9d6651bd6984'	System	05 Sep 2020 16:03:37
User entered 'None (0)'	System	05 Sep 2020 16:03:37

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-05T12:02:11', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '6ccaf805-d1aa-4c2c-bd0b-9d6651bd6984'	System	05 Sep 2020 16:03:37
User entered 'None (0)'	System	05 Sep 2020 16:03:37

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 23:01:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-05T12:02:12', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '6ccaf805-d1aa-4c2c-bd0b-9d6651bd6984'	System	05 Sep 2020 16:03:37
User entered 'None (0)'	System	05 Sep 2020 16:03:37

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 23:01:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-05T12:02:14', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '6ccaf805-d1aa-4c2c-bd0b-9d6651bd6984'	System	05 Sep 2020 16:03:37
User entered 'None (0)'	System	05 Sep 2020 16:03:37

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-05T12:02:16', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '6ccaf805-d1aa-4c2c-bd0b-9d6651bd6984'	System	05 Sep 2020 16:03:37
User entered 'None (0)'	System	05 Sep 2020 16:03:37



**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-05T12:02:18', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '6ccaf805-d1aa-4c2c-bd0b-9d6651bd6984'	System	05 Sep 2020 16:03:37
User entered 'None (0)'	System	05 Sep 2020 16:03:37

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 23:01:47

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 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-05T12:02:20', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '6ccaf805-d1aa-4c2c-bd0b-9d6651bd6984'	System	05 Sep 2020 16:03:37
User entered 'No (N)'	System	05 Sep 2020 16:03:37

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-05T12:02:23', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '6ccaf805-d1aa-4c2c-bd0b-9d6651bd6984'	System	05 Sep 2020 16:03:37
User entered '05 Sep 2020 12:02'	System	05 Sep 2020 16:03:37

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 19:37:35

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 19:37:35

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
Data entry locked.	System	03 Sep 2020 19:37:35
User entered 'Day 4'	System	03 Sep 2020 19:37:35

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 23:01:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-06T18:13:38', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '3ac223be-5b2f-4a3d-b990-f1da46b25de5'	System	06 Sep 2020 22:13:59
User entered 'None (0)'	System	06 Sep 2020 22:13:59

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-06T18:13:40', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '3ac223be-5b2f-4a3d-b990-f1da46b25de5'	System	06 Sep 2020 22:13:59
User entered 'None (0)'	System	06 Sep 2020 22:13:59



US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 23:01:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-06T18:13:42', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '3ac223be-5b2f-4a3d-b990-f1da46b25de5'	System	06 Sep 2020 22:13:59
User entered 'None (0)'	System	06 Sep 2020 22:13:59

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 23:01:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-06T18:13:44', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '3ac223be-5b2f-4a3d-b990-f1da46b25de5'	System	06 Sep 2020 22:13:59
User entered 'None (0)'	System	06 Sep 2020 22:13:59

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-06T18:13:45', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '3ac223be-5b2f-4a3d-b990-f1da46b25de5'	System	06 Sep 2020 22:13:59
User entered 'None (0)'	System	06 Sep 2020 22:13:59

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 23:01:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-06T18:13:47', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '3ac223be-5b2f-4a3d-b990-f1da46b25de5'	System	06 Sep 2020 22:13:59
User entered 'None (0)'	System	06 Sep 2020 22:13:59

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 23:01:47

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 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-06T18:13:49', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '3ac223be-5b2f-4a3d-b990-f1da46b25de5'	System	06 Sep 2020 22:13:59
User entered 'No (N)'	System	06 Sep 2020 22:13:59

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-06T18:13:56', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '3ac223be-5b2f-4a3d-b990-f1da46b25de5'	System	06 Sep 2020 22:13:59
User entered '06 Sep 2020 18:13'	System	06 Sep 2020 22:13:59

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '06 Sep 2020 12:00'	System	03 Sep 2020 19:37:35

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '07 Sep 2020 11:59'	System	03 Sep 2020 19:37:35



US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
Data entry locked.	System	03 Sep 2020 19:37:35
User entered 'Day 5'	System	03 Sep 2020 19:37:35

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-07T18:56:24', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '8e3e2a5a-fd7f-495d-8116-e92dfef2a458'	System	07 Sep 2020 22:56:46
User entered 'None (0)'	System	07 Sep 2020 22:56:46

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-07T18:56:27', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '8e3e2a5a-fd7f-495d-8116-e92dfef2a458'	System	07 Sep 2020 22:56:46
User entered 'None (0)'	System	07 Sep 2020 22:56:46

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 23:01:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-07T18:56:29', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '8e3e2a5a-fd7f-495d-8116-e92dfef2a458'	System	07 Sep 2020 22:56:46
User entered 'None (0)'	System	07 Sep 2020 22:56:46

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 23:01:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-07T18:56:31', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '8e3e2a5a-fd7f-495d-8116-e92dfef2a458'	System	07 Sep 2020 22:56:46
User entered 'None (0)'	System	07 Sep 2020 22:56:46

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-07T18:56:33', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '8e3e2a5a-fd7f-495d-8116-e92dfef2a458'	System	07 Sep 2020 22:56:46
User entered 'None (0)'	System	07 Sep 2020 22:56:46

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-07T18:56:35', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '8e3e2a5a-fd7f-495d-8116-e92dfef2a458'	System	07 Sep 2020 22:56:46
User entered 'None (0)'	System	07 Sep 2020 22:56:46

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 23:01:47

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 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-07T18:56:38', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '8e3e2a5a-fd7f-495d-8116-e92dfef2a458'	System	07 Sep 2020 22:56:46
User entered 'No (N)'	System	07 Sep 2020 22:56:46



**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-07T18:56:41', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '8e3e2a5a-fd7f-495d-8116-e92dfef2a458'	System	07 Sep 2020 22:56:46
User entered '07 Sep 2020 18:56'	System	07 Sep 2020 22:56:46

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '07 Sep 2020 12:00'	System	03 Sep 2020 19:37:35

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '08 Sep 2020 11:59'	System	03 Sep 2020 19:37:35

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
Data entry locked.	System	03 Sep 2020 19:37:35
User entered 'Day 6'	System	03 Sep 2020 19:37:35

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-09T10:43:26', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '3cf337aa-559f-4daa-8472-e0431d40094f'	System	09 Sep 2020 14:43:44
User entered 'None (0)'	System	09 Sep 2020 14:43:44

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-09T10:43:28', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '3cf337aa-559f-4daa-8472-e0431d40094f'	System	09 Sep 2020 14:43:44
User entered 'None (0)'	System	09 Sep 2020 14:43:44

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 23:01:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-09T10:43:29', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '3cf337aa-559f-4daa-8472-e0431d40094f'	System	09 Sep 2020 14:43:44
User entered 'None (0)'	System	09 Sep 2020 14:43:44

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 23:01:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-09T10:43:31', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '3cf337aa-559f-4daa-8472-e0431d40094f'	System	09 Sep 2020 14:43:44
User entered 'None (0)'	System	09 Sep 2020 14:43:44



**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-09T10:43:33', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '3cf337aa-559f-4daa-8472-e0431d40094f'	System	09 Sep 2020 14:43:44
User entered 'None (0)'	System	09 Sep 2020 14:43:44

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-09T10:43:35', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '3cf337aa-559f-4daa-8472-e0431d40094f'	System	09 Sep 2020 14:43:44
User entered 'None (0)'	System	09 Sep 2020 14:43:44

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 23:01:47

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 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-09T10:43:37', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '3cf337aa-559f-4daa-8472-e0431d40094f'	System	09 Sep 2020 14:43:44
User entered 'No (N)'	System	09 Sep 2020 14:43:44

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-09T10:43:40', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '3cf337aa-559f-4daa-8472-e0431d40094f'	System	09 Sep 2020 14:43:44
User entered '09 Sep 2020 10:43'	System	09 Sep 2020 14:43:44

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '08 Sep 2020 12:00'	System	03 Sep 2020 19:37:35

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '09 Sep 2020 11:59'	System	03 Sep 2020 19:37:35

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 23:01:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
Data entry locked.	System	03 Sep 2020 19:37:35
User entered 'Day 7'	System	03 Sep 2020 19:37:35

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-09T20:12:20', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '0af4103f-8db2-426d-8e64-834ba59eee1e'	System	10 Sep 2020 00:12:37
User entered 'None (0)'	System	10 Sep 2020 00:12:37



**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-09T20:12:22', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '0af4103f-8db2-426d-8e64-834ba59eee1e'	System	10 Sep 2020 00:12:37
User entered 'None (0)'	System	10 Sep 2020 00:12:37

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 23:01:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-09T20:12:24', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '0af4103f-8db2-426d-8e64-834ba59eee1e'	System	10 Sep 2020 00:12:37
User entered 'None (0)'	System	10 Sep 2020 00:12:37

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 23:01:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-09T20:12:26', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '0af4103f-8db2-426d-8e64-834ba59eee1e'	System	10 Sep 2020 00:12:37
User entered 'None (0)'	System	10 Sep 2020 00:12:37

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-09T20:12:28', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '0af4103f-8db2-426d-8e64-834ba59eee1e'	System	10 Sep 2020 00:12:37
User entered 'None (0)'	System	10 Sep 2020 00:12:37

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-09T20:12:30', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '0af4103f-8db2-426d-8e64-834ba59eee1e'	System	10 Sep 2020 00:12:37
User entered 'None (0)'	System	10 Sep 2020 00:12:37

US3672407

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 23:01:47

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 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-09T20:12:32', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '0af4103f-8db2-426d-8e64-834ba59eee1e'	System	10 Sep 2020 00:12:37
User entered 'No (N)'	System	10 Sep 2020 00:12:37

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2020-09-09T20:12:34', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '0af4103f-8db2-426d-8e64-834ba59eee1e'	System	10 Sep 2020 00:12:37
User entered '09 Sep 2020 20:12'	System	10 Sep 2020 00:12:37

**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '09 Sep 2020 12:00'	System	03 Sep 2020 19:37:35



**US3672407**

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

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

**Generated On: 11 Aug 2021 23:01:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:58:18
User entered '10 Sep 2020 11:59'	System	03 Sep 2020 19:37:35

**US3672407**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:16:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Sep 2020 16:54:26

**US3672407**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:16:12
User entered '12 Sep 2020'	(b) (4), (b) (6)	12 Sep 2020 16:54:26

US3672407

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:16:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Sep 2020 16:54:26

**US3672407**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:16:12
User entered empty.	(b) (4), (b) (6)	12 Sep 2020 16:54:26

**US3672407**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:16:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Sep 2020 16:54:29

**US3672407**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:01:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User entered 'I'	System	12 Sep 2020 16:54:29

**US3672407**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:14:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 17:23:05



**US3672407**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:14:40
User entered '17 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 17:23:05

**US3672407**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:14:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	17 Sep 2020 17:23:05

**US3672407**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:14:40
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 17:23:05

**US3672407**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 19:14:43
		17 Sep 2020 17:23:12

**US3672407**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:01:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User entered 'I'	System	17 Sep 2020 17:23:12

**US3672407**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 18:12:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 20:35:44

**US3672407**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 18:12:40
User entered '24 Sep 2020'	(b) (4), (b) (6)	07 Oct 2020 20:35:44

**US3672407**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Oct 2020 18:12:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	07 Oct 2020 20:35:44



**US3672407**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Oct 2020 18:12:40
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:35:44

**US3672407**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Oct 2020 18:13:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 20:35:47

**US3672407**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:01:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User entered 'I'	System	07 Oct 2020 20:35:47

US3672407

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:01:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
User closed query 'Please complete the rest of the V2/D29 folder' (Site from CRA).	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 20:47:29
Query 'Please complete the rest of the V2/D29 folder' answered with 'updated / completed. ' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 20:46:37
User opened query 'Please complete the rest of the V2/D29 folder' (Site from CRA).	(b) (4), (b) (6)	19 Oct 2020 18:16:30
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 18:15:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 20:36:04

**US3672407**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Oct 2020 18:15:34
User entered '29 Sep 2020'	(b) (4), (b) (6)	07 Oct 2020 20:36:04

US3672407

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:01:47

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Dec 2020 16:02:45
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 20:46:44
User entered 'Clinic (Clinic)' reason for change:	(b) (4), (b) (6)	22 Oct 2020 20:46:44
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 18:15:34
User entered 'Home (Home)'	(b) (4), (b) (6)	07 Oct 2020 20:36:04

**US3672407**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:01:47**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User entered 'VISIT2'	System	07 Oct 2020 20:36:04

US3672407

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	20 Oct 2020 16:15:25



US3672407

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:02:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 16:15:25

**US3672407**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:02:47
User entered '29 Sep 2020'	(b) (4), (b) (6)	20 Oct 2020 16:15:25

**US3672407**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:02:47
User entered '12:22'	(b) (4), (b) (6)	20 Oct 2020 16:15:25

US3672407

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User entered '29 Sep 2020 12:22'	System	20 Oct 2020 16:15:25

US3672407

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:02:47
User entered '98.3' F	(b) (4), (b) (6)	20 Oct 2020 16:15:25

**US3672407**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 23:01:47**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:02:47
User entered 'Oral (Oral)'	(b) (4), (b) (6)	20 Oct 2020 16:15:25

**US3672407**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 23:01:47**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:02:47
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 16:15:25

US3672407

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:02:47
User entered '61'	(b) (4), (b) (6)	20 Oct 2020 16:15:25



**US3672407**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 23:01:47**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User entered 'bpm'	System	20 Oct 2020 16:15:25

US3672407

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:02:47
User entered '12'	(b) (4), (b) (6)	20 Oct 2020 16:15:25

US3672407

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User entered 'breaths/min'	System	20 Oct 2020 16:15:25

US3672407

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:02:47
User entered '108'	(b) (4), (b) (6)	20 Oct 2020 16:15:25

US3672407

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User entered 'mmHg'	System	20 Oct 2020 16:15:25

**US3672407**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:02:47
User entered '67'	(b) (4), (b) (6)	20 Oct 2020 16:15:25

US3672407

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User entered 'mmHg'	System	20 Oct 2020 16:15:25

**US3672407**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 23:01:47**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	20 Oct 2020 16:15:25



US3672407

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	20 Oct 2020 17:02:47
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 16:15:25

**US3672407**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:02:47
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 16:15:25

**US3672407**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:02:47
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 16:15:25

**US3672407**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User entered empty.	System	20 Oct 2020 16:15:25

US3672407

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:02:47
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 16:15:25

**US3672407**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 23:01:47**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:02:47
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 16:15:25

**US3672407**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 23:01:47**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:02:47
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 16:15:25

**US3672407**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 23:01:47**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:02:47
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 16:15:25



**US3672407**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 23:01:47**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User entered empty.	System	20 Oct 2020 16:15:25

US3672407

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:02:47
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 16:15:25

US3672407

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User entered empty.	System	20 Oct 2020 16:15:25

US3672407

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:02:47
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 16:15:25

**US3672407**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 23:01:47**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User entered empty.	System	20 Oct 2020 16:15:25

**US3672407**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:02:47
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 16:15:25

US3672407

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User entered empty.	System	20 Oct 2020 16:15:25

US3672407

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:01:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:02:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 16:16:13



US3672407

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:01:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:02:52
User entered '29 Sep 2020'	(b) (4), (b) (6)	20 Oct 2020 16:16:13

US3672407

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:47

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:03:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 16:16:30

US3672407

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:47

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:03:03
User entered '29 Sep 2020'	(b) (4), (b) (6)	20 Oct 2020 16:16:30

**US3672407**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:01:47**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:03:03
User entered 'Urine (URINE)'	(b) (4), (b) (6)	20 Oct 2020 16:16:30

**US3672407**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:01:47**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:03:03
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	20 Oct 2020 16:16:30

**US3672407**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:01:47**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 17:03:03
	(b) (4), (b) (6)	20 Oct 2020 16:16:30

**US3672407**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:01:47**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:03:03
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 16:16:30

**US3672407**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:01:47**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:03:03
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 16:16:30



**US3672407**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User entered empty.	System	20 Oct 2020 16:16:30

**US3672407**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:01:47**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 17:03:06
		20 Oct 2020 16:18:13

US3672407

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:01:47

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
User closed query 'Per CDM: Requery: Response noted, however please consider to specify the AE in "If reason is Physician decision, withdrawal of consent, Protocol deviation or other specify" .Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 06:39:45
Query 'Per CDM: Requery: Response noted, however please consider to specify the AE in "If reason is Physician decision, withdrawal of consent, Protocol deviation or other specify" .Thank you.' answered with 'Specified due to AE arrhythmia ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 15:02:23
User opened query 'Per CDM: Requery: Response noted, however please consider to specify the AE in "If reason is Physician decision, withdrawal of consent, Protocol deviation or other specify" .Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 09:02:32
User closed query 'Per CDM: The reason mentioned is dose withheld due to AE , kindly specify the AE related to this in the reason section below .Thank you' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 08:50:14
Query 'Per CDM: The reason mentioned is dose withheld due to AE , kindly specify the AE related to this in the reason section below .Thank you' answered with 'AE line #1, arrhythmia ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 16:36:57
User opened query 'Per CDM: The reason mentioned is dose withheld due to AE , kindly specify the AE related to this in the reason section below .Thank you' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 10:58:43
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:03:06
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	(b) (4), (b) (6)	20 Oct 2020 16:18:13

US3672407

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:39:26
DataPoint Un-verified.	(b) (4), (b) (6)	30 Oct 2020 15:02:09
User entered 'Due to AE on 7 SEP 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 15:02:09
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:03:06
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 16:18:13

US3672407

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:01:47

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User entered empty.	System	20 Oct 2020 16:18:13

US3672407

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:01:47

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 17:03:06
		20 Oct 2020 16:18:13

US3672407

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	20 Oct 2020 17:03:06
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 16:18:13

US3672407

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User entered empty.	System	20 Oct 2020 16:18:13



US3672407

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 17:03:06
		20 Oct 2020 16:18:13

US3672407

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:03:06
User entered empty.	System	20 Oct 2020 16:18:13

US3672407

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:01:47

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User entered empty.	System	20 Oct 2020 16:18:13

US3672407

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:01:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 18:17:23
		07 Oct 2020 20:37:15

US3672407

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:01:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 18:17:23
User entered '29 Sep 2020'	(b) (4), (b) (6)	07 Oct 2020 20:37:15

US3672407

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:01:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:03:41
User closed query 'Please provide source for the collection time. Thanks' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 17:03:39
Query 'Please provide source for the collection time. Thanks' answered with 'updated to reflect source.' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 16:18:43
User entered '13:28' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 16:18:35
DataPoint Un-verified.	(b) (4), (b) (6)	19 Oct 2020 18:18:22
User opened query 'Please provide source for the collection time. Thanks' (Site from CRA).	(b) (4), (b) (6)	19 Oct 2020 18:18:20
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 18:17:23
User entered '13:03'	(b) (4), (b) (6)	07 Oct 2020 20:37:15

**US3672407**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User entered '29 Sep 2020 13:28'	System	20 Oct 2020 16:18:35
User entered '29 Sep 2020 13:03'	System	07 Oct 2020 20:37:15

US3672407

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 23:01:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:04:26
User entered '29 Sep 2020'	(b) (4), (b) (6)	07 Oct 2020 20:36:51



**US3672407**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 23:01:47**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	07 Oct 2020 20:36:51

**US3672407**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 23:01:47**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Oct 2020 18:20:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 20:36:51

US3672407

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:01:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:04:26
User closed query 'Per source, the collection time for swab is 13:30. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 17:04:23
Query 'Per source, the collection time for swab is 13:30. Please verify and update accordingly.' answered with 'updated to reflect source.' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 16:19:08
User entered '13:03' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Oct 2020 16:18:56
User opened query 'Per source, the collection time for swab is 13:30. Please verify and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	19 Oct 2020 18:20:26
User entered '12:40'	(b) (4), (b) (6)	07 Oct 2020 20:36:51

**US3672407**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User entered '29 Sep 2020 13:03'	System	20 Oct 2020 16:18:56
User entered '29 Sep 2020 12:40'	System	07 Oct 2020 20:36:51

**US3672407**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 23:01:47**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	07 Oct 2020 20:36:51

**US3672407**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 23:01:47**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:04:26
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 20:36:51

**US3672407**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:04:26
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:36:51

**US3672407**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User entered empty.	System	07 Oct 2020 20:36:51



**US3672407**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Oct 2020 18:20:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 20:36:15

**US3672407**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:01:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User entered 'I'	System	07 Oct 2020 20:36:15

**US3672407**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 19:22:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 20:37:32

**US3672407**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 19:22:57
User entered '07 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 20:37:32

US3672407

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 19:22:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	07 Oct 2020 20:37:32

US3672407

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:47

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Oct 2020 19:22:57
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 20:37:32

**US3672407**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Oct 2020 19:23:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 20:37:44

**US3672407**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:01:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User entered 'I'	System	07 Oct 2020 20:37:44



**US3672407**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 19:23:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 21:51:18

**US3672407**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 19:23:03
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 21:51:18

**US3672407**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	19 Oct 2020 19:23:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	13 Oct 2020 21:51:18

**US3672407**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Oct 2020 19:23:03
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 21:51:18

**US3672407**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Oct 2020 19:23:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 21:51:20

**US3672407**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:01:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User entered 'I'	System	13 Oct 2020 21:51:20

**US3672407**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 19:40:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 15:55:38

**US3672407**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:40:16
User entered '20 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 15:55:38



**US3672407**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:40:16
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Oct 2020 15:55:38

**US3672407**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:40:16
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 15:55:38

**US3672407**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:41
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 19:40:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 15:55:42

**US3672407**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:01:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User entered 'I'	System	20 Oct 2020 15:55:42

**US3672407**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:01:47**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Dec 2020 16:03:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Nov 2020 16:12:05

**US3672407**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:03:25
User entered '26 Oct 2020'	(b) (4), (b) (6)	15 Nov 2020 16:12:05

**US3672407**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:01:47**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Dec 2020 16:03:25
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	15 Nov 2020 16:12:05

**US3672407**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:01:47**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User entered 'VISIT3'	System	15 Nov 2020 16:12:05



**US3672407**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Dec 2020 16:09:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Nov 2020 16:12:39

US3672407

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:09:07
User entered '26 Oct 2020'	(b) (4), (b) (6)	15 Nov 2020 16:12:39

**US3672407**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:09:07
User entered '12:18'	(b) (4), (b) (6)	15 Nov 2020 16:12:39

**US3672407**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User entered '26 Oct 2020 12:18'	System	15 Nov 2020 16:12:39

**US3672407**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:09:07
User entered '98.7' F	(b) (4), (b) (6)	15 Nov 2020 16:12:39

**US3672407**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Dec 2020 16:09:07
User entered 'Oral (Oral)'	(b) (4), (b) (6)	15 Nov 2020 16:12:39

**US3672407**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Dec 2020 16:09:07
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 16:12:39

**US3672407**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:09:07
User entered '75'	(b) (4), (b) (6)	15 Nov 2020 16:12:39



**US3672407**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User entered 'bpm'	System	15 Nov 2020 16:12:39

**US3672407**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:09:07
User entered '16'	(b) (4), (b) (6)	15 Nov 2020 16:12:39

**US3672407**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User entered 'breaths/min'	System	15 Nov 2020 16:12:39

**US3672407**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Dec 2020 16:09:07
User entered '113'	(b) (4), (b) (6)	15 Nov 2020 16:12:39

**US3672407**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User entered 'mmHg'	System	15 Nov 2020 16:12:39

**US3672407**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Dec 2020 16:09:07
User entered '68'	(b) (4), (b) (6)	15 Nov 2020 16:12:39

**US3672407**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User entered 'mmHg'	System	15 Nov 2020 16:12:39

**US3672407**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27



**US3672407**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27

US3672407

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:01:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Dec 2020 16:09:11
User entered 'No (N)'	(b) (4), (b) (6)	15 Nov 2020 16:12:45

**US3672407**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Dec 2020 16:09:11
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 16:12:45

**US3672407**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:01:47**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:09:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Nov 2020 16:15:37

**US3672407**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:01:47**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:09:49
User entered '26 Oct 2020'	(b) (4), (b) (6)	15 Nov 2020 16:15:37

**US3672407**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Dec 2020 16:09:49
User entered '12:48'	(b) (4), (b) (6)	15 Nov 2020 16:15:37

**US3672407**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User entered '26 Oct 2020 12:48'	System	15 Nov 2020 16:15:37

US3672407

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:10:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Dec 2020 16:09:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Nov 2020 16:15:42



**US3672407**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:01:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:27
User entered 'I'	System	15 Nov 2020 16:15:42

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51
Data entry locked.	System	03 Sep 2020 19:37:35
User entered 'Day 64'	System	03 Sep 2020 19:37:35

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

US3672407

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51



**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51



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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51



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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

**US3672407**

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

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

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**Generated On: 11 Aug 2021 23:01:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

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**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51
Data entry locked.	System	03 Sep 2020 19:37:35
User entered '03 Nov 2020 00:01'	System	03 Sep 2020 19:37:35

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51
Data entry locked.	System	03 Sep 2020 19:37:35
User entered '07 Nov 2020 23:59'	System	03 Sep 2020 19:37:35

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51
Data entry locked.	System	03 Sep 2020 19:37:35
User entered 'Day 71'	System	03 Sep 2020 19:37:35

**US3672407**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51



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**Generated On: 11 Aug 2021 23:01:47**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

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**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

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**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51



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**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

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**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

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**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

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**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 23:01:47**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

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**Folder: Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 23:01:47**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

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**Generated On: 11 Aug 2021 23:01:47**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

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**Folder: Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 23:01:47**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51



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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 23:01:47**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

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**Folder: Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 23:01:47**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

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**Folder: Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 23:01:47**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
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[Date and time of submission](#)

Audit	User	Time (GMT)
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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
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Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51
Data entry locked.	System	03 Sep 2020 19:37:35
User entered '10 Nov 2020 00:01'	System	03 Sep 2020 19:37:35



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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51
Data entry locked.	System	03 Sep 2020 19:37:35
User entered '14 Nov 2020 23:59'	System	03 Sep 2020 19:37:35

**US3672407**

**Folder: Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51
Data entry locked.	System	03 Sep 2020 19:37:35
User entered 'Day 78'	System	03 Sep 2020 19:37:35

**US3672407**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

US3672407

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

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**Folder: Safety Follow Up Diary (1)**

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[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
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**Folder: Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 23:01:47**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

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**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

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**Folder: Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 23:01:47**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51



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**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

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**Folder: Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 23:01:47**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

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**Folder: Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 23:01:47**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

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**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51



**US3672407**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51



US3672407

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:01:47

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

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**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51

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**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51
Data entry locked.	System	03 Sep 2020 19:37:35
User entered '17 Nov 2020 00:01'	System	03 Sep 2020 19:37:35

**US3672407**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 03:30:51
Data entry locked.	System	03 Sep 2020 19:37:35
User entered '21 Nov 2020 23:59'	System	03 Sep 2020 19:37:35

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 03:30:51



**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 03:30:51



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 03:30:51

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 03:30:51

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 03:30:51



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 03:30:51

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 03:30:51

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 03:30:51

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 03:30:51

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 03:30:51



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 03:30:51

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 03:30:51

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 03:30:51

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 03:30:51

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 03:30:51



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 03:30:51

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 03:30:51

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 03:30:51



**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[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 (d02044d764cc41db)', Time: '2021-03-03T07:47:46-05:00', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '438da5e7-a381-4954-bb74-9e049c4acd74'	System	03 Mar 2021 12:48:01
User entered 'No (N)'	System	03 Mar 2021 12:48:01

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

Have you been exposed to someone with 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 (d02044d764cc41db)', Time: '2021-03-03T07:47:52-05:00', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '438da5e7-a381-4954-bb74-9e049c4acd74'	System	03 Mar 2021 12:48:01
User entered 'No (N)'	System	03 Mar 2021 12:48:01

**US3672407**

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2021-03-03T07:47:55-05:00', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '438da5e7-a381-4954-bb74-9e049c4acd74'	System	03 Mar 2021 12:48:01
User entered '03 Mar 2021 07:47:55'	System	03 Mar 2021 12:48:01

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[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 (d02044d764cc41db)', Time: '2021-03-06T07:53:28-05:00', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '7277bcb1-792c-4d61-8554-f12a0dd28777'	System	06 Mar 2021 12:53:47
User entered 'No (N)'	System	06 Mar 2021 12:53:47

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

Have you been exposed to someone with 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 (d02044d764cc41db)', Time: '2021-03-06T07:53:39-05:00', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '7277bcb1-792c-4d61-8554-f12a0dd28777'	System	06 Mar 2021 12:53:47
User entered 'No (N)'	System	06 Mar 2021 12:53:47



**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2021-03-06T07:53:42-05:00', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '7277bcb1-792c-4d61-8554-f12a0dd28777'	System	06 Mar 2021 12:53:47
User entered '06 Mar 2021 07:53:42'	System	06 Mar 2021 12:53:47

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[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 (d02044d764cc41db)', Time: '2021-03-13T11:51:49-05:00', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '74788408-ab23-4e23-b4d6-c19baf6b7230'	System	13 Mar 2021 16:52:03
User entered 'No (N)'	System	13 Mar 2021 16:52:03

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Have you been exposed to someone with 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 (d02044d764cc41db)', Time: '2021-03-13T11:51:52-05:00', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '74788408-ab23-4e23-b4d6-c19baf6b7230'	System	13 Mar 2021 16:52:03
User entered 'No (N)'	System	13 Mar 2021 16:52:03

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2021-03-13T11:51:56-05:00', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '74788408-ab23-4e23-b4d6-c19baf6b7230'	System	13 Mar 2021 16:52:03
User entered '13 Mar 2021 11:51:56'	System	13 Mar 2021 16:52:03

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 03:30:51



**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[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 (d02044d764cc41db)', Time: '2021-03-20T05:02:17-04:00', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'ddea902f-8479-4374-979f-af22ebe4ee51'	System	20 Mar 2021 09:02:35
User entered 'No (N)'	System	20 Mar 2021 09:02:35

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

Have you been exposed to someone with 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 (d02044d764cc41db)', Time: '2021-03-20T05:02:26-04:00', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'ddea902f-8479-4374-979f-af22ebe4ee51'	System	20 Mar 2021 09:02:35
User entered 'No (N)'	System	20 Mar 2021 09:02:35

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2021-03-20T05:02:28-04:00', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'ddea902f-8479-4374-979f-af22ebe4ee51'	System	20 Mar 2021 09:02:35
User entered '20 Mar 2021 05:02:28'	System	20 Mar 2021 09:02:35

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 03:30:51



**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[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 (d02044d764cc41db)', Time: '2021-03-27T07:52:44-04:00', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'b4ecbb0a-e8c6-4058-acf9-7d2116a32d8d'	System	27 Mar 2021 11:53:00
User entered 'No (N)'	System	27 Mar 2021 11:53:00

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

Have you been exposed to someone with 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 (d02044d764cc41db)', Time: '2021-03-27T07:52:48-04:00', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'b4ecbb0a-e8c6-4058-acf9-7d2116a32d8d'	System	27 Mar 2021 11:53:00
User entered 'No (N)'	System	27 Mar 2021 11:53:00

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2021-03-27T07:52:52-04:00', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'b4ecbb0a-e8c6-4058-acf9-7d2116a32d8d' User entered '27 Mar 2021 07:52:52'	System	27 Mar 2021 11:53:00
	System	27 Mar 2021 11:53:00

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[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 (d02044d764cc41db)', Time: '2021-04-03T06:07:14-04:00', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'aa4dad79-2bb3-42e9-81d5-c6c20d901a84'	System	03 Apr 2021 10:07:29
User entered 'No (N)'	System	03 Apr 2021 10:07:29

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

Have you been exposed to someone with 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 (d02044d764cc41db)', Time: '2021-04-03T06:07:17-04:00', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'aa4dad79-2bb3-42e9-81d5-c6c20d901a84'	System	03 Apr 2021 10:07:29
User entered 'No (N)'	System	03 Apr 2021 10:07:29



**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2021-04-03T06:07:21-04:00', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'aa4dad79-2bb3-42e9-81d5-c6c20d901a84'	System	03 Apr 2021 10:07:29
User entered '03 Apr 2021 06:07:21'	System	03 Apr 2021 10:07:29

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[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 (d02044d764cc41db)', Time: '2021-04-10T05:12:27-04:00', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'f5c74279-9145-43dc-9c65-eb2a9ffca87f'	System	10 Apr 2021 09:12:51
User entered 'No (N)'	System	10 Apr 2021 09:12:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

Have you been exposed to someone with 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 (d02044d764cc41db)', Time: '2021-04-10T05:12:45-04:00', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'f5c74279-9145-43dc-9c65-eb2a9ffca87f'	System	10 Apr 2021 09:12:51
User entered 'No (N)'	System	10 Apr 2021 09:12:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2021-04-10T05:12:48-04:00', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: 'f5c74279-9145-43dc-9c65-eb2a9ffca87f' User entered '10 Apr 2021 05:12:48'	System	10 Apr 2021 09:12:51
	System	10 Apr 2021 09:12:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 03:30:51



**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[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 (d02044d764cc41db)', Time: '2021-04-28T08:54:44-04:00', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '46761563-c1f4-4d17-a560-e220d65a9a12' User entered 'No (N)'	System	29 Apr 2021 00:05:18
	System	29 Apr 2021 00:05:18

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

Have you been exposed to someone with 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 (d02044d764cc41db)', Time: '2021-04-28T08:54:49-04:00', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '46761563-c1f4-4d17-a560-e220d65a9a12'	System	29 Apr 2021 00:05:18
User entered 'No (N)'	System	29 Apr 2021 00:05:18

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2021-04-28T08:54:55-04:00', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '46761563-c1f4-4d17-a560-e220d65a9a12'	System	29 Apr 2021 00:05:18
User entered '28 Apr 2021 08:54:55'	System	29 Apr 2021 00:05:18



**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[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 (d02044d764cc41db)', Time: '2021-05-01T04:51:09-04:00', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '4fdb5e7c-16d4-4a2e-82d6-b8c327d1c62c'	System	01 May 2021 08:51:24
User entered 'No (N)'	System	01 May 2021 08:51:24

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Have you been exposed to someone with 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 (d02044d764cc41db)', Time: '2021-05-01T04:51:12-04:00', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '4fdb5e7c-16d4-4a2e-82d6-b8c327d1c62c'	System	01 May 2021 08:51:24
User entered 'No (N)'	System	01 May 2021 08:51:24

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2021-05-01T04:51:15-04:00', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '4fdb5e7c-16d4-4a2e-82d6-b8c327d1c62c'	System	01 May 2021 08:51:24
User entered '01 May 2021 04:51:15'	System	01 May 2021 08:51:24

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 03:30:51



**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 03:30:51



**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 03:30:51



**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 03:30:51



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 03:30:51



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 03:30:51



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 03:30:51



**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 03:30:51



**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 03:30:51



**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 03:30:51



**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 03:30:51



**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 03:30:51



**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 03:30:51



**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 03:30:51



**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 03:30:51



**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 03:30:51



**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 03:30:51



**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 03:30:51



**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 03:30:51



**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 03:30:51



**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 03:30:51



**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 03:30:51



**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 03:30:51



**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 03:30:51



**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 03:30:51



**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 03:30:51



**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 03:30:51



**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 03:30:51



**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 03:30:51



**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 03:30:51



**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 03:30:51

**US3672407**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:01:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 03:30:51
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 03:30:51

US3672407

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 23:01:47**

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 13:53:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2021-03-03T07:47:27-05:00', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '07fdb349-f36b-4f9e-bff9-cae8ef6dd5ed'	System	03 Mar 2021 12:47:41
User entered 'No (N)'	System	03 Mar 2021 12:47:41

**US3672407**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:53:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d02044d764cc41db)', Time: '2021-03-03T07:47:32-05:00', User OID: 'PatientReportedOutcome (US3672407)', ODM File OID: '07fdb349-f36b-4f9e-bff9-cae8ef6dd5ed' User entered '03 Mar 2021 07:47:32'	System	03 Mar 2021 12:47:41
	System	03 Mar 2021 12:47:41

**US3672407**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 17:24:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 20:24:39



**US3672407**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 17:24:10
User entered '24 Nov 2020'	(b) (4), (b) (6)	06 Jan 2021 20:24:39

**US3672407**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 17:24:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	06 Jan 2021 20:24:39

**US3672407**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 17:24:10
User entered empty.	(b) (4), (b) (6)	06 Jan 2021 20:24:39

**US3672407**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:01:47**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Feb 2021 17:24:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 20:25:43

**US3672407**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:01:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:53:02
User entered 'I'	System	06 Jan 2021 20:25:43

**US3672407**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:36:33
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:41:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 20:26:21

US3672407

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:36:33
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:41:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User closed query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab (Single): Sample dated 28-Jan-2021 is reported under OL-1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 09:54:53
Query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab (Single): Sample dated 28-Jan-2021 is reported under OL-1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 21:46:51
User opened query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab (Single): Sample dated 28-Jan-2021 is reported under OL-1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 09:46:28
User entered '28 Dec 2020'	(b) (4), (b) (6)	06 Jan 2021 20:26:21

**US3672407**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:36:33
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:41:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	06 Jan 2021 20:26:21



**US3672407**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:36:33
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:41:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered empty.	(b) (4), (b) (6)	06 Jan 2021 20:26:21

**US3672407**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:01:47**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:36:33
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:41:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 20:26:38

**US3672407**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:01:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:36:33
User entered 'I'	System	06 Jan 2021 20:26:38

**US3672407**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:36:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:04:46
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Feb 2021 14:05:26

US3672407

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:36:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:04:46
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28JAN2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Else Clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 07:17:19
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28JAN2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Else Clarify, Thank you' answered with 'in preclarus portal' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 21:46:12
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28JAN2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Else Clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 13:18:33
User entered '02 Feb 2021'	(b) (4), (b) (6)	03 Feb 2021 14:05:26

**US3672407**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:36:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:04:46
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 14:05:26

**US3672407**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:36:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:04:46
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 14:05:26

**US3672407**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:01:47**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:36:33
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:04:53
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 19:42:31



**US3672407**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:01:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:36:33
User entered 'I'	System	23 Feb 2021 19:42:31

**US3672407**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:36:33
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:49:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 19:42:44

**US3672407**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:36:33
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:49:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered '23 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 19:42:44

**US3672407**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:36:33
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:49:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:42:44

**US3672407**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:36:33
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:49:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:42:44

**US3672407**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:01:47**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:36:33
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:49:30
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 19:42:50

**US3672407**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:01:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:36:33
User entered '1'	System	23 Feb 2021 19:42:50

**US3672407**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:01:47**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:07:31



**US3672407**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:01:47**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered '06 Apr 2021'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:07:31

US3672407

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:01:47

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 15:34:44
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:07:31

**US3672407**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:01:47**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	06 Apr 2021 20:07:31

**US3672407**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:07:38

US3672407

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:07:38

**US3672407**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:07:38

**US3672407**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 20:07:38

US3672407

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:47

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:07:38



**US3672407**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:07:38

US3672407

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:47

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:07:38

US3672407

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:07:38

**US3672407**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 20:07:38

US3672407

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:07:38

**US3672407**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 20:07:38

US3672407

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:07:38

**US3672407**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 20:07:38



US3672407

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:07:38

**US3672407**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 20:07:38

US3672407

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:01:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:07:44

**US3672407**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:01:47**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:07:44

**US3672407**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:01:47**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:07:57

US3672407

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:01:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered '06 Apr 2021'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:07:57

**US3672407**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:01:47**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered '10:02'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:07:57

**US3672407**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:01:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '06 Apr 2021 10:02'	System	06 Apr 2021 20:07:57



US3672407

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:01:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:06:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Feb 2021 21:38:16

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:01:47**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:06:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered '28 Jan 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:38:16

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:01:47**

[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 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:06:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:38:16

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:01:47**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered 'UNBLND_DECIDE'	System	17 Feb 2021 21:38:16

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:01:47**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:06:36
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered '28 Jan 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:39:41

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:01:47**

[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 14:55:03
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:14:29

US3672407

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 23:01:47

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:06:36
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User closed query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	(b) (4), (b) (6)	19 Feb 2021 04:43:23
Query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' answered with 'Please clarify what data is missing. ' (Site from System).	(b) (4), (b) (6)	17 Feb 2021 21:40:22
User opened query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	System	17 Feb 2021 21:39:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Feb 2021 21:39:41

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:01:47**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:37:18
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Mar 2021 19:10:05
User entered empty. WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:14:29



US3672407

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 23:01:47

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:06:36
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered '28 Jan 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:39:41

US3672407

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 23:01:47

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:37:18
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
DataPoint Un-verified.	(b) (4), (b) (6)	11 Mar 2021 19:10:05
Signature has been broken.	(b) (4), (b) (6)	11 Mar 2021 19:10:05
User entered 'Placebo (Placebo)' reason for change:	(b) (4), (b) (6)	11 Mar 2021 19:10:05
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:06:36
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered empty.	(b) (4), (b) (6)	17 Feb 2021 21:39:41

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:01:47**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:06:36
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:39:41

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:01:47**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:06:36
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered 'Not Administered (NA)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:39:41

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:01:47**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:06:36
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:39:41

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:01:47**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered '1'	System	17 Feb 2021 21:39:41

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:01:47**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered 'I'	System	17 Feb 2021 21:39:41

US3672407

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:01:47

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:08:11
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered empty.	(b) (4)	17 Feb 2021 21:41:31
	(b) (4), (b) (6)	



US3672407

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:01:47

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:08:11
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered empty.	(b) (4)	17 Feb 2021 21:41:31
	(b) (4), (b) (6)	

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:01:47**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered empty.	System	17 Feb 2021 21:41:31
DataPoint set to visible.	System	17 Feb 2021 21:39:41

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:01:47**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:08:11
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered empty.	(b) (4)	17 Feb 2021 21:41:31
	(b) (4), (b) (6)	

US3672407

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:01:47

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:08:11
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered empty.	(b) (4)	17 Feb 2021 21:41:31
	(b) (4), (b) (6)	

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:01:47**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered empty.	System	17 Feb 2021 21:41:31
DataPoint set to visible.	System	17 Feb 2021 21:39:41

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	17 Feb 2021 21:41:31

US3672407

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:08:11
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:41:31

US3672407

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:08:11
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered '28 Jan 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:41:31



**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:01:47**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:08:11
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered '10:26'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:41:31

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered '28 Jan 2021 10:26'	System	17 Feb 2021 21:41:31

US3672407

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:08:11
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered '98.4' F	(b) (4), (b) (6)	17 Feb 2021 21:41:31

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:08:11
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:41:31

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:01:47**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:08:11
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered empty.	(b) (4)	17 Feb 2021 21:41:31
	(b) (4), (b) (6)	

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:08:11
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered '68'	(b) (4), (b) (6)	17 Feb 2021 21:41:31

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered 'bpm'	System	17 Feb 2021 21:41:31

US3672407

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:08:11
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered '16'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:41:31



**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered 'breaths/min'	System	17 Feb 2021 21:41:31

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:08:11
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered '115'	(b) (4), (b) (6)	17 Feb 2021 21:41:31

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered 'mmHg'	System	17 Feb 2021 21:41:31

US3672407

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:08:11
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered '79'	(b) (4), (b) (6)	17 Feb 2021 21:41:31

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered 'mmHg'	System	17 Feb 2021 21:41:31

US3672407

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 23:01:47

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:08:11
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered empty.	(b) (4)	17 Feb 2021 21:41:31
	(b) (4), (b) (6)	

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:01:47**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:08:11
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered empty.	(b) (4)	17 Feb 2021 21:41:31
	(b) (4), (b) (6)	

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:01:47**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered empty.	System	17 Feb 2021 21:41:31
DataPoint set to visible.	System	17 Feb 2021 21:39:41



US3672407

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	11 Mar 2021 19:10:46

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:01:47**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:41:19
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Mar 2021 19:10:46

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:01:47**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:41:19
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered '28 Jan 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:10:46

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:01:47**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:41:19
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered '11:21'	(b) (4), (b) (6)	11 Mar 2021 19:10:46

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:01:47**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered '28 Jan 2021 11:21'	System	11 Mar 2021 19:10:46

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:01:47**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:41:19
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered '98.4' F	(b) (4), (b) (6)	11 Mar 2021 19:10:46

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:01:47**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:41:19
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Mar 2021 19:10:46

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:01:47**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:41:19
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 19:10:46



**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:01:47**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:41:19
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered '58'	(b) (4), (b) (6)	11 Mar 2021 19:10:46

US3672407

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered 'bpm'	System	11 Mar 2021 19:10:46

US3672407

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:41:19
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered '14'	(b) (4), (b) (6)	11 Mar 2021 19:10:46

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:01:47**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered 'breaths/min'	System	11 Mar 2021 19:10:46

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:01:47**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:41:19
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered '138'	(b) (4), (b) (6)	11 Mar 2021 19:10:46

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:01:47**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered 'mmHg'	System	11 Mar 2021 19:10:46

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:01:47**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:41:19
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered '87'	(b) (4), (b) (6)	11 Mar 2021 19:10:46

US3672407

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered 'mmHg'	System	11 Mar 2021 19:10:46



US3672407

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:01:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:08:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Feb 2021 21:41:40

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:01:47**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:08:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered '28 Jan 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:41:40

US3672407

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:47

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:08:28
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:42:02

US3672407

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:47

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:08:28
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered '28 Jan 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:42:02

US3672407

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:01:47

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:08:28
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:42:02

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:01:47**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:08:28
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:42:02

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:01:47**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:08:28
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:42:02

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:01:47**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:08:28
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered empty.	(b) (4), (b) (6)	17 Feb 2021 21:42:02



**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:01:47**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:08:28
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:42:02

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:01:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered empty.	System	17 Feb 2021 21:42:02

US3672407

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:01:47

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:08:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:42:29

US3672407

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:01:47

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:08:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered empty.	(b) (4)	17 Feb 2021 21:42:29
	(b) (4), (b) (6)	

US3672407

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:01:47

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 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:08:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:42:29

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:01:47**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered 'mRNA-1273'	System	17 Feb 2021 21:42:29
DataPoint set to visible.	System	17 Feb 2021 21:39:41

US3672407

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:01:47

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:08:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered '28 Jan 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:42:29

US3672407

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:01:47

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:08:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered '10:50'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:42:29



**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:01:47**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered '28 Jan 2021 10:50'	System	17 Feb 2021 21:42:29

US3672407

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:01:47

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:08:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:42:29

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:01:47**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:08:51
User entered 'ONCE'	System	17 Feb 2021 21:42:29

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:01:47**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered 'INTRAMUSCULAR'	System	17 Feb 2021 21:42:29

US3672407

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:01:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:09:00
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:43:15

US3672407

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:01:47

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:09:00
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered '28 Jan 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:43:15

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:01:47**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:09:00
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered '10:21'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:43:15

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:01:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered '28 Jan 2021 10:21'	System	17 Feb 2021 21:43:15



**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 23:01:47**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:09:08
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:44:26

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 23:01:47**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:09:08
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered '28 Jan 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:44:26

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 23:01:47**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:09:08
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered '10:07'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:44:26

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 23:01:47**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered '28 Jan 2021 10:07'	System	17 Feb 2021 21:44:26

US3672407

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:01:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:09:13
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:44:30

**US3672407**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:01:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:55:03
User entered 'I'	System	17 Feb 2021 21:44:30

**US3672407**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:09:39
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:44:54

**US3672407**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:09:39
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered '05 Feb 2021'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:44:54



**US3672407**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:09:39
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:44:54

US3672407

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:01:47

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:09:39
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:44:54

**US3672407**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:01:47**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:09:43
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 21:44:59

**US3672407**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:01:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
User entered 'I'	System	17 Feb 2021 21:44:59

**US3672407**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:01:47**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
User entered '1'	System	17 Feb 2021 21:44:59
DataPoint set to visible.	System	17 Feb 2021 21:44:59

**US3672407**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:01:47**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:52:01
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:06:45

**US3672407**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:01:47**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:52:02
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered '11 Mar 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:06:45

US3672407

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:01:47

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:37:33
DataPoint Verified.	(b) (4)	21 Apr 2021 15:05:22
User closed query 'Patient came into the clinic for this visit. Please update response to Clinic. Thanks' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 15:05:21
Query 'Patient came into the clinic for this visit. Please update response to Clinic. Thanks' answered with 'Updated' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 13:11:17
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 17:53:17
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 17:53:17
User opened query 'Patient came into the clinic for this visit. Please update response to Clinic. Thanks' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 14:51:59
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered 'Home (Home)'	(b) (4), (b) (6)	11 Mar 2021 19:06:45



**US3672407**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:01:47**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
User entered 'OLD29'	System	11 Mar 2021 19:06:45

**US3672407**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	11 Mar 2021 19:08:33

**US3672407**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:53:18
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:08:33

**US3672407**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:53:18
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered '11 Mar 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:08:33

**US3672407**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:01:47**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:53:18
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered '09:57'	(b) (4), (b) (6)	11 Mar 2021 19:08:33

**US3672407**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
User entered '11 Mar 2021 09:57'	System	11 Mar 2021 19:08:33

**US3672407**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:53:18
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered '98.7' F	(b) (4), (b) (6)	11 Mar 2021 19:08:33

**US3672407**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:53:18
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:08:33



**US3672407**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:01:47**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:53:18
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:08:33

**US3672407**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:53:18
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered '62'	(b) (4), (b) (6)	11 Mar 2021 19:08:33

**US3672407**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
User entered 'bpm'	System	11 Mar 2021 19:08:33

US3672407

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:01:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:53:18
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered '15'	(b) (4), (b) (6)	11 Mar 2021 19:08:33

**US3672407**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
User entered 'breaths/min'	System	11 Mar 2021 19:08:33

**US3672407**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:53:18
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered '147'	(b) (4), (b) (6)	11 Mar 2021 19:08:33

**US3672407**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
User entered 'mmHg'	System	11 Mar 2021 19:08:33

**US3672407**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:53:18
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered '77'	(b) (4), (b) (6)	11 Mar 2021 19:08:33



**US3672407**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
User entered 'mmHg'	System	11 Mar 2021 19:08:33

**US3672407**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:01:47**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	11 Mar 2021 19:08:33

**US3672407**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:01:47**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:53:18
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:08:33

US3672407

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:53:18
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered '11 Mar 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:08:33

**US3672407**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:01:47**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:53:18
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered '10:46'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:08:33

**US3672407**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:01:47**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
User entered '11 Mar 2021 10:46'	System	11 Mar 2021 19:08:33

US3672407

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:53:18
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered '98.7' F	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:08:33

**US3672407**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:01:47**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:53:18
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:08:33



**US3672407**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:01:47**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:53:18
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 19:08:33

**US3672407**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:01:47**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:53:18
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered '62'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:08:33

**US3672407**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:01:47**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
User entered 'bpm'	System	11 Mar 2021 19:08:33

US3672407

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:53:18
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered '14'	(b) (4), (b) (6)	11 Mar 2021 19:08:33

US3672407

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
User entered 'breaths/min'	System	11 Mar 2021 19:08:33

**US3672407**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:01:47**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:53:18
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered '120'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:08:33

US3672407

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
User entered 'mmHg'	System	11 Mar 2021 19:08:33

**US3672407**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 23:01:47**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:53:18
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered '73'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:08:33



US3672407

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:01:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
User entered 'mmHg'	System	11 Mar 2021 19:08:33

US3672407

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:01:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:53:26
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Mar 2021 19:09:04
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 19:08:53

**US3672407**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:01:47**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:53:26
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered '11 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Mar 2021 19:09:04
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 19:08:53

**US3672407**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:01:47**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:53:42
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:09:13

**US3672407**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:01:47**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:53:42
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered '11 Mar 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:09:13

**US3672407**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:01:47**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:53:42
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:09:13

**US3672407**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:01:47**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:53:42
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:09:13

**US3672407**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:01:47**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:53:42
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:09:13



**US3672407**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:01:47**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:53:42
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:09:13

**US3672407**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:01:47**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:53:42
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:09:13

**US3672407**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:01:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
User entered empty.	System	11 Mar 2021 19:09:13

**US3672407**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:01:47**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:54:00
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:09:38

**US3672407**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:01:47**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:54:00
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:09:38

US3672407

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:01:47

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:54:00
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 19:09:38

US3672407

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:01:47

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
User entered 'mRNA-1273'	System	11 Mar 2021 19:09:38
DataPoint set to visible.	System	17 Feb 2021 21:44:59

US3672407

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:01:47

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:54:00
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered '11 Mar 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:09:38



US3672407

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:01:47

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:54:00
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered '10:15'	(b) (4), (b) (6)	11 Mar 2021 19:09:38

**US3672407**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:01:47**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
User entered '11 Mar 2021 10:15'	System	11 Mar 2021 19:09:38

US3672407

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:01:47

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:54:00
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:09:38

**US3672407**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:01:47**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:54:00
User entered 'ONCE'	System	11 Mar 2021 19:09:38

US3672407

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:01:47

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
User entered 'INTRAMUSCULAR'	System	11 Mar 2021 19:09:38

US3672407

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:01:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:54:05
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:09:42

**US3672407**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:01:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
User entered 'I'	System	11 Mar 2021 19:09:42

**US3672407**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:50:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Apr 2021 16:49:42



**US3672407**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:50:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered '18 Mar 2021'	(b) (4), (b) (6)	01 Apr 2021 16:49:42

**US3672407**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:50:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:49:42

**US3672407**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:01:47**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:50:07
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 16:49:42

**US3672407**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:01:47**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:50:10
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Mar 2021 21:13:22

**US3672407**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:01:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:19
User entered 'I'	System	31 Mar 2021 21:13:22

**US3672407**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:01:47**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:06:41

**US3672407**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:01:47**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered '06 Apr 2021'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:06:41

**US3672407**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:01:47**

[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 15:34:44
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:06:41



**US3672407**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:01:47**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	06 Apr 2021 20:06:41

**US3672407**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:06:47

**US3672407**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:06:47

**US3672407**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:06:47

**US3672407**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 20:06:47

**US3672407**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:06:47

**US3672407**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:06:47

**US3672407**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:06:47



**US3672407**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:06:47

**US3672407**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 20:06:47

US3672407

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:01:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:06:47

**US3672407**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 20:06:47

**US3672407**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:06:47

**US3672407**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 20:06:47

**US3672407**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:06:47

**US3672407**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:01:47**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 20:06:47



**US3672407**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:01:47**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:06:53

**US3672407**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:01:47**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:06:53

**US3672407**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:01:47**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:07:17

**US3672407**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:01:47**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered '06 Apr 2021'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:07:17

**US3672407**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:01:47**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:34:44
User entered '10:02'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 20:07:17

**US3672407**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:01:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '06 Apr 2021 10:02'	System	06 Apr 2021 20:07:17

**US3672407**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 11 Aug 2021 23:01:47**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:14:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:05:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 16:20:29

US3672407

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:01:47

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Dec 2020 16:11:20
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Ventricular arrhythmias and cardiac arrest, PT: Ventricular extrasystoles, LLT: Premature ventricular contractions - version MedDRA\23.0.	Coder Import (b) (4)	30 Nov 2020 20:25:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	30 Nov 2020 20:25:02
Data point term sent to Coder	System	30 Nov 2020 20:24:17
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 20:23:51
Coding entries removed.	(b) (4), (b) (6)	30 Nov 2020 20:23:51
User entered 'Premature ventricular contractions' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Nov 2020 20:23:51
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:05:43
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Arrhythmia, LLT: Arrhythmia - version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 16:23:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	20 Oct 2020 16:23:45
Data point term sent to Coder	System	20 Oct 2020 16:22:45
User entered 'arrhythmia'	(b) (4), (b) (6)	20 Oct 2020 16:21:55



**US3672407**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:05:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 16:21:55

**US3672407**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:05:43
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 16:21:55

**US3672407**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:05:43
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 16:21:55

**US3672407**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:05:43
User entered '07 Sep 2020'	(b) (4), (b) (6)	20 Oct 2020 16:21:55

**US3672407**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:05:43
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 16:21:55

**US3672407**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:01:47**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 16:21:55

US3672407

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:01:47

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:15:45
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 or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 16:08:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
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 or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 21:48:52
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 21:48:44
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 21:48:44
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 or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 05:10:20
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:05:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 16:21:55

**US3672407**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:01:47**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:15:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 21:48:44
User entered '24 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 21:48:44
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:05:43
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 16:21:55



**US3672407**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:01:47**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:05:43
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 16:21:55

**US3672407**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:01:47**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 16:21:55

**US3672407**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:05:43
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	20 Oct 2020 16:21:55

**US3672407**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:05:43
User entered 'No (N)'	(b) (4), (b) (6)	20 Oct 2020 16:21:55

**US3672407**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:05:43
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 16:21:55

**US3672407**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:05:43
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 16:21:55

**US3672407**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:05:43
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 16:21:55

US3672407

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:01:47

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:05:43
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 16:21:55



US3672407

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:01:47

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:05:43
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 16:21:55

**US3672407**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:05:43
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 16:21:55

**US3672407**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:05:43
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 16:21:55

**US3672407**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:05:43
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 16:21:55

**US3672407**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:05:43
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 16:21:55

**US3672407**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:05:43
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 16:21:55

**US3672407**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:05:43
User entered 'Related (RELATED)'	(b) (4), (b) (6)	20 Oct 2020 16:21:55

**US3672407**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:05:43
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	20 Oct 2020 16:21:55



**US3672407**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:05:43
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4), (b) (6)	20 Oct 2020 16:21:55

**US3672407**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:01:47**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:05:43
User entered 'I'	(b) (4), (b) (6)	20 Oct 2020 16:21:55

**US3672407**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:05:43
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 16:21:55

**US3672407**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:05:43
User entered '0'	(b) (4), (b) (6)	20 Oct 2020 16:21:55

**US3672407**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 20:15:45
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 21:48:44
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 21:48:44
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:05:43
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	20 Oct 2020 16:21:55

**US3672407**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:01:47**

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:05:43
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 16:21:55

**US3672407**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:05:43
User entered empty.	(b) (4), (b) (6)	20 Oct 2020 16:21:55

**US3672407**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Oct 2020 16:21:55



**US3672407**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Oct 2020 16:21:55

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 23:01:47

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:14:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:16:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 16:04:24

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:01:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:17:15
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 AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;FERROUS FUMARATE;NORETHISTERONE ACETATE, PRODUCTSYNONYM: BLISOVI 24 FE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Sep 2020 08:07:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Sep 2020 08:07:50
Data point term sent to Coder	System	04 Sep 2020 16:05:54
User entered 'blisovi fe 24'	(b) (4), (b) (6)	04 Sep 2020 16:05:35

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:01:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 16:05:35

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered 'CONTRACEPTION'	(b) (4), (b) (6)	04 Sep 2020 16:05:35

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:01:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered 'I'	(b) (4), (b) (6)	04 Sep 2020 16:05:35

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:01:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	04 Sep 2020 16:05:35

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:01:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:05:35



US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:01:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered 'once daily (QD)'	(b) (4), (b) (6)	04 Sep 2020 16:05:35

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:01:47

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:05:35

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:01:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Sep 2020 16:05:35

US3672407

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:01:47**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:05:35

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered 'UN UNK 2016'	(b) (4), (b) (6)	04 Sep 2020 16:05:35

US3672407

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 16:05:35

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 16:05:35

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:01:47**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:05:35



US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:01:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:17:15
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 16:05:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 16:05:43
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 16:05:43
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 16:05:35
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:05:35

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 16:05:35

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 16:05:35

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:01:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 16:05:35

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:01:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: SERTRALINE HYDROCHLORIDE, PRODUCTSYNONYM: ZOLOFT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 16:13:40
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 16:13:40
	(b) (4)	
Data point term sent to Coder	System	04 Sep 2020 16:12:16
User entered 'ZOLOFT'	(b) (4), (b) (6)	04 Sep 2020 16:11:36

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:01:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 16:11:36

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 23:01:47**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered 'DEPRESSION'	(b) (4), (b) (6)	04 Sep 2020 16:11:36

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 23:01:47**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered '50'	(b) (4), (b) (6)	04 Sep 2020 16:11:36



US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:01:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Sep 2020 16:11:36

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:01:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:11:36

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:01:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered 'once daily (QD)'	(b) (4), (b) (6)	04 Sep 2020 16:11:36

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:01:47

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:11:36

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 23:01:47**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Sep 2020 16:11:36

US3672407

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 23:01:47**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:11:36

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 23:01:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered 'UN UNK 2016'	(b) (4), (b) (6)	04 Sep 2020 16:11:36

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:01:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 16:11:36



**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 23:01:47**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 16:11:36

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:01:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:11:36

US3672407

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 23:01:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 16:11:36

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 23:01:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 16:11:36

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 23:01:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 16:11:36

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 23:01:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 16:11:36

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:01:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:17:15
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 16:14:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 16:14:45
Data point term sent to Coder	System	04 Sep 2020 16:14:22
User entered 'VITAMIN D'	(b) (4), (b) (6)	04 Sep 2020 16:13:40

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:01:47**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 16:13:40



**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:01:47**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered 'HEALTH MAINTENANCE'	(b) (4), (b) (6)	04 Sep 2020 16:13:40

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:01:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 18:04:30
DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 14:29:43
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate' answered with 'Updated dosage per subject.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 13:48:47
DataPoint Un-verified.	(b) (4), (b) (6)	09 Oct 2020 13:48:28
User entered '10000' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 13:48:28
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 05:41:10
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered '1'	(b) (4), (b) (6)	04 Sep 2020 16:13:40

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:01:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 14:29:41
DataPoint Un-verified.	(b) (4), (b) (6)	09 Oct 2020 13:51:00
User entered 'IU (IU)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 13:51:00
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	04 Sep 2020 16:13:40

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:01:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:13:40

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:01:47**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered 'once daily (QD)'	(b) (4), (b) (6)	04 Sep 2020 16:13:40

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:01:47**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:13:40

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:01:47**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Sep 2020 16:13:40

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:01:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:13:40



**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:01:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered 'UN UNK 2020'	(b) (4), (b) (6)	04 Sep 2020 16:13:40

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:01:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 16:13:40

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:01:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	09 Oct 2020 14:29:36
User closed query 'Per source, the end date is 25Sep2020. Please verify and update. Thanks!' (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 14:29:34
Query 'Per source, the end date is 25Sep2020. Please verify and update. Thanks!' answered with 'Updated per source.' (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 13:51:08
DataPoint Un-verified.	(b) (4), (b) (6)	09 Oct 2020 13:49:18
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	09 Oct 2020 13:49:18
User opened query 'Per source, the end date is 25Sep2020. Please verify and update. Thanks!' (Site from CRA).	(b) (4), (b) (6)	08 Oct 2020 19:13:24
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 16:13:40

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:01:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	09 Oct 2020 14:29:37
DataPoint Un-verified.	(b) (4), (b) (6)	09 Oct 2020 13:49:18
User entered '25 Sep 2020' reason for change: New Information	(b) (4), (b) (6)	09 Oct 2020 13:49:18
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:13:40

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:01:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 16:13:40

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:01:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:48
User entered '1'	System	04 Sep 2020 16:13:40

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:01:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:48
User entered '1'	System	04 Sep 2020 16:13:40

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:01:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:48
User entered '804 (804)'	System	04 Sep 2020 16:13:40



US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:01:47

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:12:33
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: QUERCETIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 05:47:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 05:47:31
User closed query 'Per MM, Please clarify Name of medication' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 09:46:20
Data point term sent to Coder	System	30 Sep 2020 14:35:11
Query 'Per MM, Please clarify Name of medication' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 14:34:59
User closed query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	System	30 Sep 2020 14:34:48
Query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	30 Sep 2020 14:34:48
DataPoint Un-verified.	(b) (4), (b) (6)	30 Sep 2020 14:34:38
User entered 'QUERCETINE' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Sep 2020 14:34:38

PRODUCTION RELEASE (v12.003  
EAB) (1725)

1656 of 1714

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:01:47

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User opened query 'Per MM, Please clarify Name of medication ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 18:32:01
User opened query 'CDM Coding: This medication cannot be referred in the standard coding dictionary. Please verify the spelling of this medication. If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.' (Site from System).	Coder Import (b) (4) (b) (4)	10 Sep 2020 09:33:31
Data point term sent to Coder	System	04 Sep 2020 16:19:33
User entered 'overcetine'	(b) (4), (b) (6)	04 Sep 2020 16:18:40

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:01:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 16:18:40

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:01:47**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered 'HEALTH MANAGEMENT'	(b) (4), (b) (6)	04 Sep 2020 16:18:40

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:01:47**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered 'l'	(b) (4), (b) (6)	04 Sep 2020 16:18:40

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:01:47**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	04 Sep 2020 16:18:40

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:01:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:18:40

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:01:47**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered 'once daily (QD)'	(b) (4), (b) (6)	04 Sep 2020 16:18:40



US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:01:47

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:18:40

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:01:47**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Sep 2020 16:18:40

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:01:47**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:18:40

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:01:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered 'UN Jul 2020'	(b) (4), (b) (6)	04 Sep 2020 16:18:40

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:01:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 16:18:40

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:01:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	09 Oct 2020 14:29:57
User closed query 'Per source, the end date is 25Sep2020. Please verify and update. Thanks!' (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 14:29:55
Query 'Per source, the end date is 25Sep2020. Please verify and update. Thanks!' answered with 'Updated per source.' (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 13:43:39
DataPoint Un-verified.	(b) (4), (b) (6)	09 Oct 2020 13:41:25
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	09 Oct 2020 13:41:25
User opened query 'Per source, the end date is 25Sep2020. Please verify and update. Thanks!' (Site from CRA).	(b) (4), (b) (6)	08 Oct 2020 19:12:29
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 16:18:40

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:01:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	09 Oct 2020 14:29:58
DataPoint Un-verified.	(b) (4), (b) (6)	09 Oct 2020 13:41:25
User entered '25 Sep 2020' reason for change: New Information	(b) (4), (b) (6)	09 Oct 2020 13:41:25
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 16:18:40

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:01:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 15:17:15
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 16:18:40



**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:01:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:27
User entered '1'	System	04 Sep 2020 16:18:40

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:01:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:27
User entered '1'	System	04 Sep 2020 16:18:40

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:01:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:04:27
User entered '804 (804)'	System	04 Sep 2020 16:18:40

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:01:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 14:30:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: VALACICLOVIR HYDROCHLORIDE, PRODUCTSYNONYM: VALTREX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Oct 2020 14:01:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	09 Oct 2020 14:01:28
Data point term sent to Coder	System	09 Oct 2020 13:59:54
User entered 'Valtrex'	(b) (4), (b) (6)	09 Oct 2020 13:59:01

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:01:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 14:30:23
User entered 'No (N)'	(b) (4), (b) (6)	09 Oct 2020 13:59:01

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:01:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 14:30:23
User entered 'mHx: Herpes Genitalis'	(b) (4), (b) (6)	09 Oct 2020 13:59:01

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:01:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 14:30:23
User entered '500'	(b) (4), (b) (6)	09 Oct 2020 13:59:01

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:01:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 14:30:23
User entered 'mg (mg)'	(b) (4), (b) (6)	09 Oct 2020 13:59:01



US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:01:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 14:30:23
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 13:59:01

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:01:47**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 14:30:23
User entered 'as needed (PRN)'	(b) (4), (b) (6)	09 Oct 2020 13:59:01

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:01:47

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 14:30:23
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 13:59:01

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:01:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 14:30:23
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	09 Oct 2020 13:59:01

US3672407

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:01:47**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 14:30:23
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 13:59:01

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:01:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 14:30:23
User entered '17 Jun 2014'	(b) (4), (b) (6)	09 Oct 2020 13:59:01

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:01:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 14:30:23
User entered '0'	(b) (4), (b) (6)	09 Oct 2020 13:59:01

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:01:47**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 14:30:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 13:59:01



US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:01:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 14:30:23
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 13:59:01

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:01:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Oct 2020 14:30:23
User entered 'No (N)'	(b) (4), (b) (6)	09 Oct 2020 13:59:01

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:01:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 13:59:01

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:01:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 13:59:01

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:01:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Oct 2020 13:59:01

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:01:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:03:38
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 14:43:17
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Dec 2020 18:56:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Dec 2020 18:56:44
Data point term sent to Coder	System	14 Dec 2020 18:56:17
User entered 'influenza vaccine'	(b) (4), (b) (6)	14 Dec 2020 18:55:32

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:01:47**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:03:38
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 14:43:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Dec 2020 18:55:32

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:01:47**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:03:38
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 14:43:17
User entered 'influenza Prophylaxis'	(b) (4), (b) (6)	14 Dec 2020 18:55:32



**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:01:47**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:03:38
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 14:43:17
User entered 'l'	(b) (4), (b) (6)	14 Dec 2020 18:55:32

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:01:47**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:03:38
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 14:43:17
User entered 'Other (OTHER)'	(b) (4), (b) (6)	14 Dec 2020 18:55:32

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:01:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:03:38
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 14:43:17
User entered 'injection'	(b) (4), (b) (6)	14 Dec 2020 18:55:32

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:01:47**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:03:38
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 14:43:17
User entered 'once (ONCE)'	(b) (4), (b) (6)	14 Dec 2020 18:55:32

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:01:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:03:38
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 14:43:17
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 18:55:32

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:01:47**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:03:38
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 14:43:17
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	14 Dec 2020 18:55:32

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:01:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:03:38
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 14:43:17
User entered empty.	(b) (4), (b) (6)	14 Dec 2020 18:55:32

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:01:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:03:38
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 14:43:17
User entered '22 Oct 2020'	(b) (4), (b) (6)	14 Dec 2020 18:55:32



**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:01:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:03:38
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 14:43:17
User entered '0'	(b) (4), (b) (6)	14 Dec 2020 18:55:32

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:01:47**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:03:38
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 14:43:17
User entered 'No (N)'	(b) (4), (b) (6)	14 Dec 2020 18:55:32

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:01:47**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:03:38
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 14:43:17
User entered '22 Oct 2020'	(b) (4), (b) (6)	14 Dec 2020 18:55:32

US3672407

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:01:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:03:38
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 14:43:17
User entered 'No (N)'	(b) (4), (b) (6)	14 Dec 2020 18:55:32

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:01:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:03:38
User entered empty.	System	14 Dec 2020 18:55:32

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:01:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:03:38
User entered empty.	System	14 Dec 2020 18:55:32

**US3672407**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:01:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 08:03:38
User entered empty.	System	14 Dec 2020 18:55:32

US3672407

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 23:01:47

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 15:17:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 16:04:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 16:03:35



**US3672407**

**Folder: End of Study (1)**

**Form: Dosing Discontinuation**

**Generated On: 11 Aug 2021 23:01:47**

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:27:11
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:15:26
User entered '29 Sep 2020'	(b) (4), (b) (6)	09 Dec 2020 21:06:14

**US3672407**

**Folder: End of Study (1)**

**Form: Dosing Discontinuation**

**Generated On: 11 Aug 2021 23:01:47**

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:27:11
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:15:26
User entered 'AE (specify) (ADVERSE EVENT)'	(b) (4), (b) (6)	09 Dec 2020 21:06:14

US3672407

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 23:01:47

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 03:27:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:36:56
User closed query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 13:28:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:37:53
Query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 21:47:28
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 21:47:23
User entered 'AE#1' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 21:47:23
User opened query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:14:24
Query 'Per CDM: Please record AE record number instead of details. ' canceled (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:14:19
User opened query 'Per CDM: Please record AE record number instead of details. ' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 13:11:41
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 16:15:26
User entered 'PVCs'	(b) (4), (b) (6)	09 Dec 2020 21:06:14