

US3672377 (Prod: Coastal Carolina Research Center)

Generated By: KC Joubran

Generated On: 11 Aug 2021 23:00:38

All time stamps listed in this document are displayed in GMT

US3672377

Form: Participant Creation

Data signed: (b) (4) 05 Mar 2021 18:29:49

Generated On: 11 Aug 2021 23:00:38

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[Participant ID](#)

US3672377

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

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US3672377

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 21:07:06

Generated On: 11 Aug 2021 23:00:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 17 Feb 2021 21:07:06

Generated On: 11 Aug 2021 23:00:38

Date of Birth (MMM yyyy)	(b) (6) 1989
Age	31
Age Units	YEARS
Age (Derived)	31
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 21:07:06

Generated On: 11 Aug 2021 23:00:38

Date of Informed Consent ( <i>dd MMM yyyy</i> )	28 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input 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 21:07:06

Generated On: 11 Aug 2021 23:00:38

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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 21:07:06

Generated On: 11 Aug 2021 23:00:38

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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 21:07:06

Generated On: 11 Aug 2021 23:00:38

Condition	ATTENTION DEFICIT HYPERACTIVITY DISORDER
Start date (dd MMM yyyy)	UN APR 2020
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)	APR 2020
Start Year (derived)	2020
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 21:07:06

Generated On: 11 Aug 2021 23:00:38

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
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 21:07:06

Generated On: 11 Aug 2021 23:00:38

Condition	TEMPOROMANDIBULAR JOINT DISORDER
Start date (dd MMM yyyy)	UN UNK 2006
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2006
Start Year (derived)	2006
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 17 Feb 2021 21:07:06

Generated On: 11 Aug 2021 23:00:38

Condition	DERMATOGRAPHIA
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 17 Feb 2021 21:07:06

Generated On: 11 Aug 2021 23:00:38

Condition	URITICARIA
Start date (dd MMM yyyy)	UN MAY 2019
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)	MAY 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 17 Feb 2021 21:07:06

Generated On: 11 Aug 2021 23:00:38

Condition	PRUITIS
Start date (dd MMM yyyy)	UN MAY 2019
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 MAY 2019
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2019
Start Year (derived)	2019
Stop Month and Year (derived)	MAY 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 21:07:06

Generated On: 11 Aug 2021 23:00:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 AUG 2020
Time of assessment (00:00-23:59)	12:53 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 12:53
Height (xxx.x)	169.8 cm
Weight (xxx.x)	97.5 kg
BMI (xxx.x)	33.81655 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 21:07:06

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 17 Feb 2021 21:07:06

Generated On: 11 Aug 2021 23:00:38

Date of assessment (dd MMM yyyy) 28 AUG 2020

Is the participant of childbearing potential? Yes ☒  
No ☐

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

If Partner medically sterile or Other, specify \_\_\_\_\_

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

Date of surgery unknown False

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

Date of last menstruation unknown False



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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 17 Feb 2021 21:07:06

Generated On: 11 Aug 2021 23:00:38

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	28 AUG 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 21:07:06

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 21:07:06

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<b>Resides in Multi-family dwelling</b> (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
<b>Resides in high density housing</b> (e.g., high rise apartments with shared entrances or elevators)	False
<b>Resides in low density, multi-family setting without</b> (e.g., apartments complex without shared entrances or elevators, duplexes)	True
<b>Resides in a single family home</b> (i.e., detached housing)	False
<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 21:07:06

Generated On: 11 Aug 2021 23:00:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 17 Feb 2021 21:07:06

Generated On: 11 Aug 2021 23:00:38

What was the date of randomization? (dd MMM yyyy) 28 AUG 2020

What was the participant's randomization number? 109486

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 21:07:06

Generated On: 11 Aug 2021 23:00:38

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 21:07:06

Generated On: 11 Aug 2021 23:00:38

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)	28 AUG 2020
Time of assessment (00:00-23:59)	12:53 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 12:53
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	103 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 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 21:07:06

Generated On: 11 Aug 2021 23:00:38

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)	28 AUG 2020
Time of assessment (00:00-23:59)	14:00 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 14:00
Temperature (xxx.x)	99.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	103 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 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 21:07:06

Generated On: 11 Aug 2021 23:00:38

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 21:07:06

Generated On: 11 Aug 2021 23:00:38

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 21:07:06

Generated On: 11 Aug 2021 23:00:38

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) 28 AUG 2020

What was the treatment time? (00:00-23:59) 13:29 (24 HR)

Treatment Date and Time (derived) 28 AUG 2020 13:29

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 21:07:06

Generated On: 11 Aug 2021 23:00:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 AUG 2020

Collection time (00:00-23:59)

13:00 (24 HR)

Collection date and time (derived)

28 AUG 2020 13:00

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 21:07:06

Generated On: 11 Aug 2021 23:00:38

Collection date (dd MMM yyyy)			28 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:40	28 AUG 2020 12:40
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:07:06

Generated On: 11 Aug 2021 23:00:38

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 23:00:38

**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 99.0 °F

Was any **MEDICATION TAKEN today for pain or fever?** Yes ☒ No ☐

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 28 AUG 2020 13:57

PC Open Date & Time 28 AUG 2020 13:49

PC Close Date & Time 28 AUG 2020 16:19

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 23:00:38

**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 98.9 °F

Was any **MEDICATION TAKEN today for pain or fever?** Yes ☒ No ☐

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 28 AUG 2020 20:46

PC Open Date & Time 28 AUG 2020 17:14

PC Close Date & Time 29 AUG 2020 11:59



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 23:00:38

**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 98.9 °F

Was any **MEDICATION TAKEN today for pain or fever?** Yes ☒ No ☐

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 29 AUG 2020 21:37

PC Open Date & Time 29 AUG 2020 12:00

PC Close Date & Time 30 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 23:00:38

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	99.3 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	31 AUG 2020 07:22
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 23:00:38

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.2 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	31 AUG 2020 23:19
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 23:00:38

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	99.7 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False
PC Time Stamp	02 SEP 2020 00:15
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 23:00:38

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	99.2 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	03 SEP 2020 06:43
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 23:00:38

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	99.6 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	04 SEP 2020 00:37
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

DAY 8

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.9 °F

Was any **MEDICATION TAKEN** today for pain or fever? Yes ☒ No ☐

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 05 SEP 2020 08:21

PC Open Date & Time 04 SEP 2020 12:00

PC Close Date & Time 05 SEP 2020 11:59

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

DAY 9

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 98.4 °F

Was any **MEDICATION TAKEN** today for pain or fever? Yes ☒ No ☐

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 06 SEP 2020 00:00

PC Open Date & Time 05 SEP 2020 12:00

PC Close Date & Time 06 SEP 2020 11:59



US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

DAY 10

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

99.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 00:28

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

50

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

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

Yes ☐

No ☒

Please record - **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

28 AUG 2020 13:58

PC Open Date & Time

28 AUG 2020 13:49

PC Close Date & Time

28 AUG 2020 16:19

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

10

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

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

Yes ☐

No ☒

Please record - **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

28 AUG 2020 20:48

PC Open Date & Time

28 AUG 2020 17:14

PC Close Date & Time

29 AUG 2020 11:59

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:00:38

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

60

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 21:38

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:00:38

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

30

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 07:22

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:00:38

**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

31 AUG 2020 23:19

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:00:38

**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

02 SEP 2020 00:15

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:00:38

**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

03 SEP 2020 06:43

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59



US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:00:38

**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

04 SEP 2020 00:37

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:00:38

**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 ☐

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:00:38

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 13:59
PC Open Date & Time	28 AUG 2020 13:49
PC Close Date & Time	28 AUG 2020 16:19

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:00:38

**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 ☐

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:00:38

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 20:48
PC Open Date & Time	28 AUG 2020 17:14
PC Close Date & Time	29 AUG 2020 11:59

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 23:00:38

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 ☒

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 23:00:38

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 21:39
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 23:00:38

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 ☒



US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 23:00:38

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 07:22
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 23:00:38

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 ☒

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 23:00:38

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 23:19
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 23:00:38

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 ☒

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US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 23:00:38

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 00:15
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 23:00:38

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 ☒

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 23:00:38

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 06:44
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 23:00:38

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 ☒



US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 23:00:38

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 00:37
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3672377

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

**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 ☐

PC Time Stamp 05 SEP 2020 08:21

PC Open Date & Time 04 SEP 2020 12:00

PC Close Date & Time 05 SEP 2020 11:59

US3672377

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your

None ☐

**HEADACHE**

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 00:00

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3672377

Folder: Diary Dose 1 (1)

Form: Headache\_Day(10)

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

DAY 10

Select one response below to indicate the intensity of your

None ☒

**HEADACHE**

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

07 SEP 2020 00:28

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3672377

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 23:00:38

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	05 SEP 2020 08:21
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3672377

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 23:00:38

<b>TIMEPOINT</b>	DAY 9
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	06 SEP 2020 00:00
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3672377

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 11 Aug 2021 23:00:38

TIMEPOINT

DAY 10

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

No ☒

Yes ☐

PC Time stamp

07 SEP 2020 00:28

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3672377

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 21:07:06

Generated On: 11 Aug 2021 23:00:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3672377

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:07:06

Generated On: 11 Aug 2021 23:00:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672377

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 21:07:05

Generated On: 11 Aug 2021 23:00:38

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3672377

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:07:05

Generated On: 11 Aug 2021 23:00:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672377

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 21:07:06

Generated On: 11 Aug 2021 23:00:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3672377

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:07:06

Generated On: 11 Aug 2021 23:00:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672377

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 21:07:06

Generated On: 11 Aug 2021 23:00:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3672377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 21:07:06

Generated On: 11 Aug 2021 23:00:38

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)	30 SEP 2020
Time of assessment (00:00-23:59)	16:59 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 16:59
Temperature (xxx.x)	99.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	106 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)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3672377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 21:07:06

Generated On: 11 Aug 2021 23:00:38

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	



US3672377

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 21:07:06

Generated On: 11 Aug 2021 23:00:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 SEP 2020

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

US3672377

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 17 Feb 2021 21:07:06

Generated On: 11 Aug 2021 23:00:38

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	30 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3672377

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 21:07:06

Generated On: 11 Aug 2021 23:00:38

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 PHYSICIAN DECISION  
WITHDRAWAL OF  
EXPERIENCES AN AE OR SAW  
THAT, IN THE JUDGEMENT OF  
THE INVESTIGATOR, REQUIRES  
STUDY IP WITHDRAWAL DUE  
TO IT'S NATURE

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? \_\_\_\_\_

US3672377

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 21:07:06

Generated On: 11 Aug 2021 23:00:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 SEP 2020
Collection time (00:00-23:59)	17:55 (24 HR)
Collection date and time (derived)	30 SEP 2020 17:55

US3672377

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 21:07:06

Generated On: 11 Aug 2021 23:00:38

Collection date (dd MMM yyyy)			30 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:10	30 SEP 2020 17:10
Nasopharyngeal Swab 2	No		

US3672377

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:07:06

Generated On: 11 Aug 2021 23:00:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672377

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 21:07:06

Generated On: 11 Aug 2021 23:00:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3672377

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:07:06

Generated On: 11 Aug 2021 23:00:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3672377

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 21:07:06

Generated On: 11 Aug 2021 23:00:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3672377

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:07:06

Generated On: 11 Aug 2021 23:00:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672377

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 18:37:24

Generated On: 11 Aug 2021 23:00:38

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

PATIENT WAS FOLLOWING UP  
ON WORSENING  
DERMATOGRAPHISM

*If Contact Not Made, please provide Comments*

US3672377

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:07:06

Generated On: 11 Aug 2021 23:00:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672377

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 21:07:06

Generated On: 11 Aug 2021 23:00:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 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

US3672377

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 21:07:06

Generated On: 11 Aug 2021 23:00:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 OCT 2020
Time of assessment (00:00-23:59)	17:16 (24 HR)
Vital Signs Date and Time (derived)	28 OCT 2020 17:16
Temperature (xxx.x)	99.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	103 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3672377

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 21:07:06

Generated On: 11 Aug 2021 23:00:38

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.*

US3672377

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 21:07:06

Generated On: 11 Aug 2021 23:00:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 OCT 2020

Collection time (00:00-23:59)

17:40 (24 HR)

Collection date and time (derived)

28 OCT 2020 17:40



US3672377

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 21:07:06

Generated On: 11 Aug 2021 23:00:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672377

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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°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"/>

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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

Date and time of submission

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3672377

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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 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	04 NOV 2020 23:43:40
Patient Cloud Open Date & Time	04 NOV 2020 00:01
Patient Cloud Close Date & Time	08 NOV 2020 23:59

US3672377

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 NOV 2020 17:58:19
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 NOV 2020 00:08:16

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 DEC 2020 21:26:31
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>



**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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[Patient Cloud Close Date & Time](#)

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10 DEC 2020 23:59

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US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 DEC 2020 20:41:31

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 DEC 2020 18:41:31

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 DEC 2020 18:05:01
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 JAN 2021 12:44:53
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 JAN 2021 18:11:32

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 JAN 2021 18:02:03

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 JAN 2021 12:45:08

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59



US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 FEB 2021 12:05:23

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 FEB 2021 17:19:16
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 FEB 2021 18:12:59

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**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

23 FEB 2021 12:03:46

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**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

02 MAR 2021 12:03:26

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 MAR 2021 23:31:10

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**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

16 MAR 2021 13:28:48

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**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

23 MAR 2021 12:02:21

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59



US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**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

30 MAR 2021 12:00:48

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**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

08 APR 2021 13:26:24

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 APR 2021 12:53:22

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

<b>TIMEPOINT</b>	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 APR 2021 12:03:11
Patient Cloud Open Date & Time	18 APR 2021 00:01
Patient Cloud Close Date & Time	22 APR 2021 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 APR 2021 12:03:04

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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="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"/>

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

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US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**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 ☐



**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

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US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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[Patient Cloud Close Date & Time](#)

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20 MAY 2021 23:59

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US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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"/>

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**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 ☐

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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[Patient Cloud Open Date & Time](#)

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30 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 JUN 2021 23:59

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US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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"/>



**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	13 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 JUN 2021 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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"/>

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

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

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



**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 JUL 2021 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

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

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

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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[Patient Cloud Close Date & Time](#)

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22 JUL 2021 23:59

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US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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="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"/>

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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[Patient Cloud Open Date & Time](#)

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25 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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29 JUL 2021 23:59

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US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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



**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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"/>

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	15 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 AUG 2021 23:59
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US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**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 ☐



**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

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US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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"/>

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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[Patient Cloud Close Date & Time](#)

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16 SEP 2021 23:59

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US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

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

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

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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[Patient Cloud Close Date & Time](#)

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23 SEP 2021 23:59

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US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**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 ☐



**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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"/>

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	03 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 OCT 2021 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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"/>

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 OCT 2021 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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="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"/>

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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[Patient Cloud Close Date & Time](#)

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28 OCT 2021 23:59

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US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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°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"/>

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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"/>

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	14 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 NOV 2021 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**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 ☐



**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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[Patient Cloud Close Date & Time](#)

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25 NOV 2021 23:59

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US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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"/>

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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[Patient Cloud Close Date & Time](#)

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02 DEC 2021 23:59

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US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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"/>

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

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US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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"/>

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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

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 ☐



**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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[Patient Cloud Close Date & Time](#)

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23 DEC 2021 23:59

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US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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"/>

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 JAN 2022 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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

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 ☐



**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 JAN 2022 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

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03 FEB 2022 23:59

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US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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"/>

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

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US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**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 ☐



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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

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17 FEB 2022 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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24 FEB 2022 23:59

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US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**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 ☐

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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27 FEB 2022 00:01

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03 MAR 2022 23:59

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US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**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 ☐

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

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US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**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 ☐



**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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13 MAR 2022 00:01

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17 MAR 2022 23:59

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US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**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°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 ☐

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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[Patient Cloud Close Date & Time](#)

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24 MAR 2022 23:59

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US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

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

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

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

27 MAR 2022 00:01

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31 MAR 2022 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**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 ☐

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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[Patient Cloud Open Date & Time](#)

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03 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 APR 2022 23:59

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US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**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 ☐



**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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[Patient Cloud Close Date & Time](#)

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14 APR 2022 23:59

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US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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[Patient Cloud Close Date & Time](#)

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05 MAY 2022 23:59

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US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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="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"/>



**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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[Patient Cloud Close Date & Time](#)

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12 MAY 2022 23:59

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US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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[Patient Cloud Close Date & Time](#)

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26 MAY 2022 23:59

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US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**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 ☐



**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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[Patient Cloud Close Date & Time](#)

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09 JUN 2022 23:59

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US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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="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"/>

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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[Patient Cloud Close Date & Time](#)

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16 JUN 2022 23:59

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US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**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 ☐

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

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23 JUN 2022 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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="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"/>

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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[Patient Cloud Open Date & Time](#)

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26 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 JUN 2022 23:59

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US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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 <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"/>



**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 JUL 2022 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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17 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 JUL 2022 23:59

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US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**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 ☐  
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 ☐

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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[Patient Cloud Close Date & Time](#)

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28 JUL 2022 23:59

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US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**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 ☐



**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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"/>

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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[Patient Cloud Open Date & Time](#)

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07 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 AUG 2022 23:59

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US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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[Patient Cloud Open Date & Time](#)

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14 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 AUG 2022 23:59

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US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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



**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

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US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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"/>

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

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

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

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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



**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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[Patient Cloud Open Date & Time](#)

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25 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 SEP 2022 23:59

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US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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"/>

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

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US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**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 ☐

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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[Patient Cloud Open Date & Time](#)

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09 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 OCT 2022 23:59

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US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**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°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 ☐

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 OCT 2022 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3672377

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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"/>

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

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[Patient Cloud Open Date & Time](#)

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30 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 NOV 2022 23:59

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US3672377

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 11 Aug 2021 23:00:38

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		02 MAR 2021 12:03:52

US3672377

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:29:50

Generated On: 11 Aug 2021 23:00:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3672377

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:29:50

Generated On: 11 Aug 2021 23:00:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672377

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:29:50

Generated On: 11 Aug 2021 23:00:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3672377

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:29:50

Generated On: 11 Aug 2021 23:00:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3672377

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:29:50

Generated On: 11 Aug 2021 23:00:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3672377

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:29:50

Generated On: 11 Aug 2021 23:00:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672377

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:29:50

Generated On: 11 Aug 2021 23:00:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3672377

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:29:50

Generated On: 11 Aug 2021 23:00:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672377

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 15:32:51

Generated On: 11 Aug 2021 23:00:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 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

US3672377

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 15:32:51

Generated On: 11 Aug 2021 23:00:38

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) \_\_\_\_\_

US3672377

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 15:32:51

Generated On: 11 Aug 2021 23:00:38

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.*

US3672377

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 15:32:51

Generated On: 11 Aug 2021 23:00:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

1 APR 2021

Collection time (00:00-23:59)

17:15 (24 HR)

Collection date and time (derived)

1 APR 2021 17:15



US3672377

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 15:32:51

Generated On: 11 Aug 2021 23:00:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672377

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 10:27:19

Generated On: 11 Aug 2021 23:00:38

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 APR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3672377

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 10:27:19

Generated On: 11 Aug 2021 23:00:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3672377**

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

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:38**

Was Contact Attempted? Yes ☐  
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

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

Comments

*If Contact Not Made, please provide Comments*

**US3672377**

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

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:38**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3672377

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 23:00:38

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"/>

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3672377

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

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 18:29:50

Generated On: 11 Aug 2021 23:00:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE



US3672377

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 15:32:51

Generated On: 11 Aug 2021 23:00:38

Date of updated informed consent (dd MMM yyyy) 04 FEB 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 4 FEB 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_

US3672377

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 18:29:50

Generated On: 11 Aug 2021 23:00:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

4 FEB 2021

Collection time (00:00-23:59)

17:35 (24 HR)

Collection date and time (derived)

4 FEB 2021 17:35

US3672377

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Mar 2021 18:29:50

Generated On: 11 Aug 2021 23:00:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 FEB 2021
Collection time (00:00 - 23:59)	17:30
Collection Date and Time (derived)	4 FEB 2021 17:30

US3672377

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 05 Mar 2021 18:29:50

Generated On: 11 Aug 2021 23:00:38

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3672377

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Apr 2021 21:49:44

Generated On: 11 Aug 2021 23:00:38

AEID

Adverse event

TOOTH INFECTION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

09 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)

17 OCT 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 ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

308 of 2030

EAB) (1725)

US3672377

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Apr 2021 21:49:44

Generated On: 11 Aug 2021 23:00:38

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Apr 2021 21:49:44

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AEID

Adverse event

HEADACHE

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)

28 AUG 2020

Start time (00:00-23:59)

13:29 (24 HR)

AE start date and time (derived)

28 AUG 2020 13:29

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

06 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 ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Apr 2021 21:49:44

Generated On: 11 Aug 2021 23:00:38

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



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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 08 Apr 2021 21:49:44

Generated On: 11 Aug 2021 23:00:38

AEID	
Adverse event	WORSENING OF URITICARIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	21 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 08 Apr 2021 21:49:44

Generated On: 11 Aug 2021 23:00:38

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 <input checked="" type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input 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)	

US3672377

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 08 Apr 2021 21:49:44

Generated On: 11 Aug 2021 23:00:38

AEID

Adverse event

GENERALIZED PRURITIS

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)

11 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)

19 NOV 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 ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 08 Apr 2021 21:49:44

Generated On: 11 Aug 2021 23:00:38

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 <input checked="" type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 08 Apr 2021 21:49:44

Generated On: 11 Aug 2021 23:00:38

AEID

Adverse event

ANGIOEDEMA

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)

18 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)

19 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 ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 08 Apr 2021 21:49:44

Generated On: 11 Aug 2021 23:00:38

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 <input checked="" type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 08 Apr 2021 21:49:44

Generated On: 11 Aug 2021 23:00:38

AEID

Adverse event

WORSENING OF  
DERMATOGRAPHIA

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)

21 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)

04 NOV 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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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 08 Apr 2021 21:49:44

Generated On: 11 Aug 2021 23:00:38

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



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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 08 Apr 2021 21:49:44

Generated On: 11 Aug 2021 23:00:38

AEID

Adverse event

TOOTH INFECTION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

14 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

16 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 08 Apr 2021 21:49:44

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 08 Apr 2021 21:49:44

Generated On: 11 Aug 2021 23:00:38

AEID

Adverse event

PAIN SECONDARY TO TOOTH  
EXTRACTION

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)

16 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

17 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 08 Apr 2021 21:49:44

Generated On: 11 Aug 2021 23:00:38

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

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Data signed:** (b) (4) 08 Apr 2021 21:49:44

**Generated On: 11 Aug 2021 23:00:38**

---

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

Yes ☒

No ☐

---

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

---

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 20:45:24

Generated On: 11 Aug 2021 23:00:38

Name of Medication ADDERALL

Prophylaxis Yes ☐  
No ☒

Indication ADHD

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 20:45:24

Generated On: 11 Aug 2021 23:00:38

	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)	11 AUG 2020	
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)	2	
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 (2)

Data signed: (b) (4) 12 Apr 2021 20:45:24

Generated On: 11 Aug 2021 23:00:38

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication GERD

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 20:45:24

Generated On: 11 Aug 2021 23:00:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 20:45:24

Generated On: 11 Aug 2021 23:00:38

Name of Medication DEPOT PROVERA

Prophylaxis Yes ☒  
No ☐

Indication BIRTH CONTROL

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 9 1/2 WEEKS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 20:45:24

Generated On: 11 Aug 2021 23:00:38

	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)	UN OCT 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 20:45:24

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Name of Medication EXCEDRIN (UNKNOWN)

Prophylaxis Yes ☐  
No ☒

Indication HEADACHES

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 20:45:24

Generated On: 11 Aug 2021 23:00:38

	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)	28 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	06 SEP 2020	
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 20:45:24

Generated On: 11 Aug 2021 23:00:38

Name of Medication AMOXICILLIN

Prophylaxis Yes ☐  
No ☒

Indication TOOTH INFECTION

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 20:45:24

Generated On: 11 Aug 2021 23:00:38

	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)		09 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 19 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		3
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) 12 Apr 2021 20:45:24

Generated On: 11 Aug 2021 23:00:38

Name of Medication HYDROCODONE/ACETAMINOP  
HEN

Prophylaxis Yes ☐  
No ☒

Indication TOOTH INFECTION

Dose per administration 5-325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Apr 2021 20:45:24

Generated On: 11 Aug 2021 23:00:38

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	09 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	13 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	4	
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 (7)

Data signed: (b) (4) 12 Apr 2021 20:45:24

Generated On: 11 Aug 2021 23:00:38

Name of Medication ZYRTEC

Prophylaxis Yes ☐  
No ☒

Indication WORSENING OF  
DERMATOGRAPHIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Apr 2021 20:45:24

Generated On: 11 Aug 2021 23:00:38

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	21 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		04 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Apr 2021 20:45:24

Generated On: 11 Aug 2021 23:00:38

Name of Medication BENADRYL

Prophylaxis Yes ☐  
No ☒

Indication DERMATOGRAPHIA

Dose per administration 25

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 (8)

Data signed: (b) (4) 12 Apr 2021 20:45:24

Generated On: 11 Aug 2021 23:00:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Apr 2021 20:45:24

Generated On: 11 Aug 2021 23:00:38

Name of Medication CLINDAMYACIN

Prophylaxis Yes ☒  
No ☐

Indication TOOTH INFECTION

Dose per administration 300

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 (9)

Data signed: (b) (4) 12 Apr 2021 20:45:24

Generated On: 11 Aug 2021 23:00:38

	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)	08 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	17 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	4	
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 (10)

Data signed: (b) (4) 12 Apr 2021 20:45:24

Generated On: 11 Aug 2021 23:00:38

Name of Medication ALLEGRA

Prophylaxis Yes ☐  
No ☒

Indication URITICARIA

Dose per administration 180

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 (10)

Data signed: (b) (4) 12 Apr 2021 20:45:24

Generated On: 11 Aug 2021 23:00:38

	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)		19 OCT 2020
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)		2
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 (11)

Data signed: (b) (4) 12 Apr 2021 20:45:24

Generated On: 11 Aug 2021 23:00:38

Name of Medication XYZAL

Prophylaxis Yes ☐  
No ☒

Indication WORSENING OF URITICARIA

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 12 Apr 2021 20:45:24

Generated On: 11 Aug 2021 23:00:38

	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)		19 OCT 2020
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 (12)

Data signed: (b) (4) 12 Apr 2021 20:45:24

Generated On: 11 Aug 2021 23:00:38

Name of Medication HYDROCODONE/ACETAMINOP  
HEN

Prophylaxis Yes ☐  
No ☒

Indication PAIN SECONDARY TO TOOTH  
EXTRACTION

Dose per administration 325/5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 12 Apr 2021 20:45:24

Generated On: 11 Aug 2021 23:00:38

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		17 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 21:49:44

Generated On: 11 Aug 2021 23:00:38

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 08 Apr 2021 21:49:44

Generated On: 11 Aug 2021 23:00:38

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
16 MAR 2021	TOOTH EXTRACTION	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 05 Mar 2021 18:29:50

Generated On: 11 Aug 2021 23:00:38

---

Date of dosing discontinuation (dd MMM yyyy) 30 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 #5,6,7

---



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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 23:00:38

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

US3672377 (Prod: Coastal Carolina Research Center)

**US3672377**

**Form: Participant Creation**

**Generated On: 11 Aug 2021 23:00:38**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:29:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 17:32:07
User entered 'US3672377'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 16:54:43

**US3672377**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:38**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:55:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 17:06:11

US3672377

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 19:55:58
User entered '28 AUG 2020'	RWS_ENDPOINT	28 Aug 2020 16:54:44
	ENDPOINT (b) (4)	

**US3672377**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:38**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:55:58
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	28 Aug 2020 17:06:11

**US3672377**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:38**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User entered 'SCRN'	System	28 Aug 2020 17:06:11

US3672377

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 19:56:14
User entered (b) (6) 1989'	RWS_ENDPOINT	28 Aug 2020 16:54:45
	ENDPOINT (b) (4)	



**US3672377**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:00:38**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 19:56:14
User entered '31'	(b) (4), (b) (6)	28 Aug 2020 17:06:20

**US3672377**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:00:38**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User entered 'YEARS'	System	28 Aug 2020 17:06:20

**US3672377**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:00:38**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User entered '31'	System	28 Aug 2020 17:06:31

**US3672377**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:00:38**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:56:14
User entered 'Female (F)'	(b) (4), (b) (6)	28 Aug 2020 17:06:20

**US3672377**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:00:38**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:56:14
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	28 Aug 2020 17:06:20

**US3672377**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:00:38**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:56:14
User entered 'l'	(b) (4), (b) (6)	28 Aug 2020 17:06:20

**US3672377**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:00:38**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:56:14
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 17:06:20

**US3672377**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:00:38**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:56:14
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 17:06:20



**US3672377**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:00:38**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:56:14
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 17:06:20

**US3672377**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:00:38**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:56:14
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 17:06:20

**US3672377**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:00:38**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:56:14
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 17:06:20

**US3672377**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:00:38**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:56:14
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 17:06:20

**US3672377**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:00:38**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:56:14
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 17:06:20

**US3672377**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 23:00:38**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:56:14
User entered '0'	(b) (4), (b) (6)	28 Aug 2020 17:06:20

**US3672377**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:56:17
User entered '28 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 17:06:31

**US3672377**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User entered 'Aug 2020'	System	28 Aug 2020 17:06:31



**US3672377**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User entered '2020'	System	28 Aug 2020 17:06:31

**US3672377**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:00:38**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:56:17
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	28 Aug 2020 17:06:31

**US3672377**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:56:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 17:06:31

**US3672377**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:56:17
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 17:06:31

**US3672377**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:00:38**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:56:17
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 17:06:31

**US3672377**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:00:38**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:56:17
User entered 'No (N)'	(b) (4), (b) (6)	28 Aug 2020 17:06:31

**US3672377**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:00:38**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 19:56:17
User entered empty.	RWS_ENDPOINT	28 Aug 2020 16:54:44
	ENDPOINT (b) (4)	

**US3672377**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 23:00:38**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User entered '1'	System	28 Aug 2020 17:06:35



**US3672377**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:56:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 17:06:35

**US3672377**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 11 Aug 2021 23:00:38**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:56:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 14:36:39

US3672377

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 23:00:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 12:43:03
User closed query 'Per MM: please expand the abbreviation.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 11:50:22
User coded data point as SOC: Psychiatric disorders, HLGT: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: Attention deficit/hyperactivity disorder - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 18:47:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 18:47:47
Data point term sent to Coder	System	23 Sep 2020 18:46:48
Query 'Per MM: please expand the abbreviation.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 18:45:59
DataPoint Un-verified.	(b) (4), (b) (6)	23 Sep 2020 18:45:53
Coding entries removed.	(b) (4), (b) (6)	23 Sep 2020 18:45:53
User entered 'Attention deficit hyperactivity disorder' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 18:45:53
User opened query 'Per MM: please expand the abbreviation.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 20:05:24
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:56:36
User coded data point as SOC: Psychiatric disorders, HLGT: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: ADHD - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 14:38:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 14:38:46
Data point term sent to Coder	System	01 Sep 2020 14:38:00
User entered 'ADHD'	(b) (4), (b) (6)	01 Sep 2020 14:37:04

**US3672377**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:56:36
User entered 'UN Apr 2020'	(b) (4), (b) (6)	01 Sep 2020 14:37:04

**US3672377**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:00:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:56:36
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 14:37:04

**US3672377**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:00:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:56:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 14:37:04

**US3672377**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:00:38**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:56:36
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:37:04

**US3672377**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:00:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:56:36
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 14:37:04



**US3672377**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:00:38**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User entered 'Apr 2020'	System	01 Sep 2020 14:37:04

**US3672377**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:00:38**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User entered '2020'	System	01 Sep 2020 14:37:04

**US3672377**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:00:38**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User entered empty.	System	01 Sep 2020 14:37:04

**US3672377**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 23:00:38**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User entered empty.	System	01 Sep 2020 14:37:04

US3672377

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 23:00:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	29 Oct 2020 12:43:23
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 19:51:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 19:51:42
Data point term sent to Coder	System	21 Oct 2020 19:50:56
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:50:13
Coding entries removed.	(b) (4), (b) (6)	21 Oct 2020 19:50:13
User entered 'gastroesophageal reflux disease' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 19:50:13
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:56:36
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 14:38:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 14:38:46
Data point term sent to Coder	System	01 Sep 2020 14:38:00
User entered 'GERD'	(b) (4), (b) (6)	01 Sep 2020 14:37:24

**US3672377**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:56:36
User entered 'UN UNK 2007'	(b) (4), (b) (6)	01 Sep 2020 14:37:24

**US3672377**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 23:00:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:56:36
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 14:37:24

**US3672377**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 23:00:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:56:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 14:37:24



**US3672377**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 23:00:38**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:56:36
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:37:24

**US3672377**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 23:00:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:56:36
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 14:37:24

**US3672377**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 23:00:38**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User entered 'Jan 2007'	System	01 Sep 2020 14:37:24

**US3672377**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 23:00:38**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User entered '2007'	System	01 Sep 2020 14:37:24

**US3672377**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 23:00:38**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User entered empty.	System	01 Sep 2020 14:37:24

**US3672377**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 23:00:38**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User entered empty.	System	01 Sep 2020 14:37:24

US3672377

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:00:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:50:41
User closed query 'Per MM, please expand the abbreviation' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 21:36:50
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Temporomandibular joint syndrome, LLT: Temporomandibular joint disorder - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 19:52:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	21 Oct 2020 19:52:01
Data point term sent to Coder	System	21 Oct 2020 19:52:01
Query 'Per MM, please expand the abbreviation' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 19:51:18
Coding entries removed.	(b) (4), (b) (6)	21 Oct 2020 19:51:14
User entered 'temporomandibular joint disorder' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 19:51:14
User opened query 'Per MM, please expand the abbreviation' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 14:30:30
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related disorders NEC, PT: Temporomandibular joint syndrome, LLT: TMJ syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 18:50:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	01 Oct 2020 18:50:53
Data point term sent to Coder	System	01 Oct 2020 18:49:42
User entered 'TMJ'	(b) (4), (b) (6)	01 Oct 2020 18:49:05

**US3672377**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:50:41
User entered 'UN UNK 2006'	(b) (4), (b) (6)	01 Oct 2020 18:49:05



**US3672377**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 23:00:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:50:41
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 18:49:05

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Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 23:00:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	05 Nov 2020 20:50:41
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 18:49:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Oct 2020 18:49:15
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 18:49:15
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 18:49:05
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:49:05

**US3672377**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 23:00:38**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:50:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:49:05

**US3672377**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 23:00:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:50:41
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 18:49:05

**US3672377**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 23:00:38**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User entered 'Jan 2006'	System	01 Oct 2020 18:49:05

**US3672377**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 23:00:38**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User entered '2006'	System	01 Oct 2020 18:49:05

**US3672377**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 23:00:38**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User entered empty.	System	01 Oct 2020 18:49:05

**US3672377**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 23:00:38**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User entered empty.	System	01 Oct 2020 18:49:05



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Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 23:00:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:39:32
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Mechanical urticaria, LLT: Dermatographia - version MedDRA\23.0.	Coder Import (b) (4)	15 Nov 2020 16:47:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	15 Nov 2020 16:47:44
Data point term sent to Coder	System	15 Nov 2020 16:47:02
DataPoint Un-verified.	(b) (4), (b) (6)	15 Nov 2020 16:46:50
Coding entries removed.	(b) (4), (b) (6)	15 Nov 2020 16:46:50
User entered 'DERMATOGRAPHIA' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Nov 2020 16:46:50
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:50:41
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Mechanical urticaria, LLT: Dermatographia - version MedDRA\23.0.	Coder Import (b) (4)	29 Oct 2020 23:14:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	29 Oct 2020 23:14:44
User closed query 'Per DM CLR: Please specify the location (bilateral, left, right) and/or type of DERMATOGRAPHIA. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 04:02:05
Query 'Per DM CLR: Please specify the location (bilateral, left, right) and/or type of DERMATOGRAPHIA. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'updated ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 15:15:35
Data point term sent to Coder	System	27 Oct 2020 15:15:00

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Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 23:00:38

[Condition](#)

Audit	User	Time (GMT)
Coding entries removed.	(b) (4), (b) (6)	27 Oct 2020 15:14:35
User entered 'Bilateral DERMATOGRAPHIA' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 15:14:35
User opened query 'Per DM CLR: Please specify the location (bilateral, left, right) and/or type of DERMATOGRAPHIA. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 20:00:54
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Mechanical urticaria, LLT: Dermatographia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 18:51:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 18:51:57
Data point term sent to Coder	System	01 Oct 2020 18:50:42
User entered 'DERMATOGRAPHIA'	(b) (4), (b) (6)	01 Oct 2020 18:50:09

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**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:50:41
User entered 'UN UNK 2019'	(b) (4), (b) (6)	01 Oct 2020 18:50:09

**US3672377**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 23:00:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:50:41
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 18:50:09

**US3672377**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 23:00:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:50:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 18:50:09

**US3672377**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 23:00:38**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:50:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:50:09

**US3672377**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 23:00:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:50:41
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 18:50:09

**US3672377**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 23:00:38**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User entered 'Jan 2019'	System	01 Oct 2020 18:50:09



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**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 23:00:38**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User entered '2019'	System	01 Oct 2020 18:50:09

**US3672377**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 23:00:38**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User entered empty.	System	01 Oct 2020 18:50:09

**US3672377**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 23:00:38**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User entered empty.	System	01 Oct 2020 18:50:09

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Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 23:00:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:50:41
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Urticaria, LLT: Urticaria - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 05:54:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 05:54:57
Data point term sent to Coder	System	29 Oct 2020 21:14:26
User entered 'Urticaria'	(b) (4), (b) (6)	29 Oct 2020 21:14:10

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**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:50:41
User entered 'un May 2019'	(b) (4), (b) (6)	29 Oct 2020 21:14:10

**US3672377**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 23:00:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:50:41
User entered '0'	(b) (4), (b) (6)	29 Oct 2020 21:14:10

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Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 23:00:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:39:41
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Un-verified.	(b) (4), (b) (6)	15 Nov 2020 16:47:19
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Nov 2020 16:47:19
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:50:41
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 21:14:10

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Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 23:00:38

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:39:43
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Un-verified.	(b) (4), (b) (6)	15 Nov 2020 16:47:19
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Nov 2020 16:47:19
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:50:41
User entered 'un May 2019'	(b) (4), (b) (6)	29 Oct 2020 21:14:10



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**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 23:00:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:50:41
User entered '0'	(b) (4), (b) (6)	29 Oct 2020 21:14:10

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**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 23:00:38**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User entered 'May 2019'	System	29 Oct 2020 21:14:10

**US3672377**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 23:00:38**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User entered '2019'	System	29 Oct 2020 21:14:10

**US3672377**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 23:00:38**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User entered empty.	System	15 Nov 2020 16:47:19
User entered 'May 2019'	System	29 Oct 2020 21:14:10

**US3672377**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 23:00:38**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User entered empty.	System	15 Nov 2020 16:47:19
User entered '2019'	System	29 Oct 2020 21:14:10

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Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 23:00:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:50:41
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Pruritus NEC, PT: Pruritus, LLT: Pruritus - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 05:47:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 05:47:51
Data point term sent to Coder	System	29 Oct 2020 21:15:27
User entered 'Pruitis'	(b) (4), (b) (6)	29 Oct 2020 21:14:42

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**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:50:41
User entered 'un May 2019'	(b) (4), (b) (6)	29 Oct 2020 21:14:42

**US3672377**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:50:41
User entered '0'	(b) (4), (b) (6)	29 Oct 2020 21:14:42



**US3672377**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:50:41
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 21:14:42

**US3672377**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 23:00:38**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:50:41
User entered 'un May 2019'	(b) (4), (b) (6)	29 Oct 2020 21:14:42

**US3672377**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:50:41
User entered '0'	(b) (4), (b) (6)	29 Oct 2020 21:14:42

**US3672377**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User entered 'May 2019'	System	29 Oct 2020 21:14:42

**US3672377**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User entered '2019'	System	29 Oct 2020 21:14:42

**US3672377**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User entered 'May 2019'	System	29 Oct 2020 21:14:42

**US3672377**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User entered '2019'	System	29 Oct 2020 21:14:42

**US3672377**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:38**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:57:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 14:40:58



**US3672377**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:57:13
User entered '28 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 14:40:58

**US3672377**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:57:13
User entered '12:53'	(b) (4), (b) (6)	01 Sep 2020 14:40:58

US3672377

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User entered '28 Aug 2020 12:53'	System	01 Sep 2020 14:40:58

**US3672377**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:57:13
User entered '169.8' cm	(b) (4), (b) (6)	01 Sep 2020 14:40:58
DataPoint set to visible.	System	28 Aug 2020 17:06:35

US3672377

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:38

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 19:57:13
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Sep 2020 14:44:03
User entered '97.5' kg reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 14:44:03
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Sep 2020 14:40:58
User entered '97' (non-conformant).	(b) (4), (b) (6)	01 Sep 2020 14:40:58
DataPoint set to visible.	System	28 Aug 2020 17:06:35

**US3672377**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:38**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User entered '33.81655'	System	01 Sep 2020 14:44:03
User entered empty.	System	01 Sep 2020 14:40:58
DataPoint set to visible.	System	28 Aug 2020 17:06:35

US3672377

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:38

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User entered 'kg/m2'	System	01 Sep 2020 14:44:03
User entered empty.	System	01 Sep 2020 14:40:58
DataPoint set to visible.	System	28 Aug 2020 17:06:35

US3672377

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 19:57:13
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:44:03
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	01 Sep 2020 14:44:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 14:44:03
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:40:58
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:40:58



**US3672377**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:38**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:57:13
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 14:44:03
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:40:58

US3672377

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 19:57:13
User closed query 'Route of measurement is Other, however, specify is missing. Please provide.' (Site from System).	System	01 Sep 2020 14:44:14
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 14:44:14
User opened query 'Route of measurement is Other, however, specify is missing. Please provide.' (Site from System).	System	01 Sep 2020 14:44:03
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:40:58

US3672377

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 19:57:13
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:44:03
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	01 Sep 2020 14:44:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 14:44:03
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:40:58
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:40:58

**US3672377**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:38**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User entered 'bpm'	System	01 Sep 2020 14:44:03
User entered empty.	System	01 Sep 2020 14:40:58

US3672377

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 19:57:13
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:44:03
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	01 Sep 2020 14:44:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 14:44:03
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:40:58
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:40:58

US3672377

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User entered 'breaths/min'	System	01 Sep 2020 14:44:03
User entered empty.	System	01 Sep 2020 14:40:58

US3672377

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 19:57:13
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:44:03
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	01 Sep 2020 14:44:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 14:44:03
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:40:58
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:40:58

**US3672377**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:38**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User entered 'mmHg'	System	01 Sep 2020 14:44:03
User entered empty.	System	01 Sep 2020 14:40:58



US3672377

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 19:57:13
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:44:03
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	01 Sep 2020 14:44:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 14:44:03
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:40:58
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:40:58

US3672377

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User entered 'mmHg'	System	01 Sep 2020 14:44:03
User entered empty.	System	01 Sep 2020 14:40:58

**US3672377**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:38**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05

**US3672377**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:38**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05

**US3672377**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:00:38**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:57:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 14:44:44

**US3672377**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:57:18
User entered '28 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 14:44:44

**US3672377**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:57:30
User entered '28 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 14:46:21

**US3672377**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:57:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 14:46:21



**US3672377**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:57:30
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:46:21

**US3672377**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:57:30
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:46:21

**US3672377**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:57:30
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:46:21

**US3672377**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 23:00:38**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:57:30
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 14:46:21

**US3672377**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:57:30
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:46:21

**US3672377**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 23:00:38**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:57:30
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 14:46:21

**US3672377**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:00:38**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:58:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 14:46:58

**US3672377**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:58:51
User entered '28 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 14:46:58



**US3672377**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:00:38**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:58:01
User entered 'Urine (URINE)'	(b) (4), (b) (6)	01 Sep 2020 14:46:58

**US3672377**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:00:38**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:58:02
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	01 Sep 2020 14:46:58

**US3672377**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:00:38**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:58:06
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 14:46:58

**US3672377**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:00:38**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:58:07
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:46:58

**US3672377**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:00:38**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:58:09
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:46:58

**US3672377**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User entered empty.	System	01 Sep 2020 14:46:58

US3672377

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:59:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 14:48:31

US3672377

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:59:37
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 14:48:31



US3672377

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:38

**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)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:59:37
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 14:48:31

US3672377

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:38

**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)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:59:37
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 14:48:31

US3672377

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:59:37
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 14:48:31

US3672377

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:38

[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)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:59:37
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 14:48:31

US3672377

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:38

**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)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:59:37
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 14:48:31

US3672377

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:38

**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)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:59:37
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 14:48:31

US3672377

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:38

[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)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 19:59:37
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 14:48:31

US3672377

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:38

**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)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:59:37
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 14:48:31



US3672377

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:38

**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)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:59:37
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 14:48:31

US3672377

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:38

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:59:37
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 14:48:31

US3672377

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:38

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:59:37
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:48:31

**US3672377**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 23:00:38**

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 14:48:31

US3672377

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:59:37
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 14:48:31

US3672377

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:38

**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)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:59:37
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 14:48:31

US3672377

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:38

**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)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:59:37
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 14:48:31

US3672377

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:38

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)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:59:37
User entered 'I'	(b) (4), (b) (6)	01 Sep 2020 14:48:31



US3672377

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:59:37
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 14:48:31

**US3672377**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 23:00:38**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
User entered 'I'	(b) (4), (b) (6)	01 Sep 2020 14:48:31

US3672377

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 23:00:38

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:05
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 19:59:37
User entered 'RESIDENT IN A COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION.'	(b) (4), (b) (6)	01 Sep 2020 14:48:31

**US3672377**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:38**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:59:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 14:48:53

**US3672377**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:59:49
User entered '28 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 14:48:53

**US3672377**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:38**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 09 Sep 2020 19:59:49
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	01 Sep 2020 14:48:53

**US3672377**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:38**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User entered 'VISIT1'	System	01 Sep 2020 14:48:53

US3672377

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 19:59:54
User entered '28 AUG 2020'	RWS_ENDPOINT	28 Aug 2020 17:09:46
	ENDPOINT (b) (4)	



**US3672377**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 19:59:54
User entered '109486'	RWS_ENDPOINT	28 Aug 2020 17:09:46
	ENDPOINT (b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 19:59:54
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 17:09:46

US3672377

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:00:38

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)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:59:54
User closed query 'PER CDM: Please complete this section of the form.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 12:35:43
Query 'PER CDM: Please complete this section of the form.' answered with 'CONFIRMED, NO RISK FOR PT. ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 14:50:26
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 14:49:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Sep 2020 14:49:31
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 14:49:31
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 14:49:25
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 14:49:25
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 14:49:14
User opened query 'PER CDM: Please complete this section of the form.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 19:50:50

US3672377

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:00:38

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)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:59:54
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 14:49:14

**US3672377**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	09 Sep 2020 19:59:54
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 14:49:14

**US3672377**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	09 Sep 2020 19:59:54
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 14:49:14

**US3672377**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 23:00:38**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 19:59:54
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 14:49:14

US3672377

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 23:00:38

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:40:21
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 08:37:52
Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 17:04:12
User entered 'No (N)'	(b) (4), (b) (6)	09 Dec 2020 17:04:06
User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 23:11:38
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:28:38
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:28:37



**US3672377**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:00:38**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:59:58
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 14:52:17

**US3672377**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:00:38**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:59:58
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 14:52:17

**US3672377**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:00:38**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:59:58
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 14:52:17

**US3672377**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:00:38**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:59:58
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 14:52:17

US3672377

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	01 Sep 2020 14:52:17

US3672377

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 09 Sep 2020 19:59:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 14:52:17

US3672377

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 19:59:58
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:53:19
User entered '28 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 14:53:19
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:52:17
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:52:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	09 Sep 2020 19:59:58
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:53:19
Query 'Data is required. Please provide.' answered by System data change (Site from System).		01 Sep 2020 14:53:19
User entered '12:53' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 14:53:19
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:52:17
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:52:17



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User entered '28 Aug 2020 12:53'	System	01 Sep 2020 14:53:19
User entered empty.	System	01 Sep 2020 14:52:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 19:59:58
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:53:19
Query 'Data is required. Please provide.' answered by System data change (Site from System).		01 Sep 2020 14:53:19
User entered '98.9' F reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 14:53:19
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:52:17
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:52:17

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**Folder: Visit 1 Day 1**

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

**Generated On: 11 Aug 2021 23:00:38**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:59:58
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 14:53:19
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:52:17

**US3672377**

**Folder: Visit 1 Day 1**

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

**Generated On: 11 Aug 2021 23:00:38**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:59:58
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:52:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 19:59:58
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:53:19
Query 'Data is required. Please provide.' answered by System data change (Site from System).		01 Sep 2020 14:53:19
User entered '103' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 14:53:19
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:52:17
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:52:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User entered 'bpm'	System	01 Sep 2020 14:53:19
User entered empty.	System	01 Sep 2020 14:52:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 19:59:58
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:53:19
Query 'Data is required. Please provide.' answered by System data change (Site from System).		01 Sep 2020 14:53:19
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 14:53:19
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:52:17
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:52:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User entered 'breaths/min'	System	01 Sep 2020 14:53:19
User entered empty.	System	01 Sep 2020 14:52:17



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 19:59:58
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:53:19
Query 'Data is required. Please provide.' answered by System data change (Site from System).		01 Sep 2020 14:53:19
User entered '118' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 14:53:19
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:52:17
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:52:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User entered 'mmHg'	System	01 Sep 2020 14:53:19
User entered empty.	System	01 Sep 2020 14:52:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 19:59:58
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:53:19
Query 'Data is required. Please provide.' answered by System data change (Site from System).		01 Sep 2020 14:53:19
User entered '86' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 14:53:19
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:52:17
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:52:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User entered 'mmHg'	System	01 Sep 2020 14:53:19
User entered empty.	System	01 Sep 2020 14:52:17

**US3672377**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:00:38**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:59:58
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 14:52:17

**US3672377**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 23:00:38**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:59:58
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Sep 2020 14:52:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	01 Sep 2020 14:52:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 19:59:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 14:52:17



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 19:59:58
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:54:20
User entered '28 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 14:54:20
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:52:17
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:52:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 19:59:58
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:54:20
Query 'Data is required. Please provide.' answered by System data change (Site from System).		01 Sep 2020 14:54:20
User entered '14:00' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 14:54:20
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:52:17
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:52:17

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**Folder: Visit 1 Day 1**

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

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User entered '28 Aug 2020 14:00'	System	01 Sep 2020 14:54:20
User entered empty.	System	01 Sep 2020 14:52:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 19:59:58
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:54:20
Query 'Data is required. Please provide.' answered by System data change (Site from System).		01 Sep 2020 14:54:20
User entered '99.0' F reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 14:54:20
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:52:17
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:52:17

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**Folder: Visit 1 Day 1**

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

**Generated On: 11 Aug 2021 23:00:38**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 19:59:58
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 14:54:20
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:52:17

**US3672377**

**Folder: Visit 1 Day 1**

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

**Generated On: 11 Aug 2021 23:00:38**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:59:58
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:52:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 19:59:58
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:54:20
Query 'Data is required. Please provide.' answered by System data change (Site from System).		01 Sep 2020 14:54:20
User entered '103' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 14:54:20
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:52:17
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:52:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User entered 'bpm'	System	01 Sep 2020 14:54:20
User entered empty.	System	01 Sep 2020 14:52:17



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 19:59:58
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:54:20
Query 'Data is required. Please provide.' answered by System data change (Site from System).		01 Sep 2020 14:54:20
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 14:54:20
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:52:17
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:52:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User entered 'breaths/min'	System	01 Sep 2020 14:54:20
User entered empty.	System	01 Sep 2020 14:52:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 19:59:58
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:54:20
Query 'Data is required. Please provide.' answered by System data change (Site from System).		01 Sep 2020 14:54:20
User entered '138' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 14:54:20
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:52:17
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:52:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User entered 'mmHg'	System	01 Sep 2020 14:54:20
User entered empty.	System	01 Sep 2020 14:52:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	09 Sep 2020 19:59:58
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:54:20
Query 'Data is required. Please provide.' answered by System data change (Site from System).		01 Sep 2020 14:54:20
User entered '92' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 14:54:20
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Sep 2020 14:52:17
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:52:17

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User entered 'mmHg'	System	01 Sep 2020 14:54:20
User entered empty.	System	01 Sep 2020 14:52:17

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 23:00:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 20:00:04
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 14:54:31

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 23:00:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 20:00:04
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:54:31



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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:00:38

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:50:24
User closed query 'Per CDM: Please note if screening and Visit date is on the same day, kindly change the Pregnancy test performed on Visit 1 to "NO". Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 09:18:31
Query 'Per CDM: Please note if screening and Visit date is on the same day, kindly change the Pregnancy test performed on Visit 1 to "NO". Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 18:45:03
DataPoint Un-verified.	(b) (4), (b) (6)	23 Sep 2020 18:44:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 18:44:57
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 20:00:17
User opened query 'Per CDM: Please note if screening and Visit date is on the same day, kindly change the Pregnancy test performed on Visit 1 to "NO". Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 07:05:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 14:54:49

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:00:38

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:50:24
DataPoint Un-verified.	(b) (4), (b) (6)	23 Sep 2020 18:44:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 18:44:57
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 20:00:17
User entered '28 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 14:54:49

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:00:38

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:50:24
DataPoint Un-verified.	(b) (4), (b) (6)	23 Sep 2020 18:44:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 18:44:57
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 20:00:17
User entered 'Urine (URINE)'	(b) (4), (b) (6)	01 Sep 2020 14:54:49

**US3672377**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:00:38**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:50:24
DataPoint Un-verified.	(b) (4), (b) (6)	23 Sep 2020 18:44:57
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 18:44:57
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 20:00:17
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	01 Sep 2020 14:54:49

US3672377

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:00:38

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 20:00:17
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 14:54:49

**US3672377**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:00:38**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 09 Sep 2020 20:00:17
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:54:49

**US3672377**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:00:38**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 20:00:17
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:54:49

**US3672377**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User entered empty.	System	01 Sep 2020 14:54:49



**US3672377**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:00:38**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 20:00:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Aug 2020 17:51:22

**US3672377**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:00:38**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 09 Sep 2020 20:00:31
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 17:51:22

US3672377

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 20:00:31
User entered empty.	(b) (4), (b) (6)	28 Aug 2020 17:51:22

**US3672377**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:00:38**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User entered 'MRNA-1273 OR PLACEBO'	System	28 Aug 2020 17:51:22

US3672377

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:00:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 20:00:31
User entered '28 Aug 2020'	(b) (4), (b) (6)	28 Aug 2020 17:51:22

**US3672377**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 20:00:31
User entered '13:29'	(b) (4), (b) (6)	28 Aug 2020 17:51:22

**US3672377**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User entered '28 Aug 2020 13:29'	System	28 Aug 2020 17:51:22

US3672377

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 20:00:31
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	28 Aug 2020 17:51:22



US3672377

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 20:00:31
User entered 'ONCE'	System	28 Aug 2020 17:51:22

**US3672377**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:00:38**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User entered 'INTRAMUSCULAR'	System	28 Aug 2020 17:51:22

**US3672377**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:00:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 20:00:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 14:55:39

US3672377

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:00:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:00:36
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	01 Sep 2020 14:57:07
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		01 Sep 2020 14:57:07
User closed query 'The Collection Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	01 Sep 2020 14:57:07
User closed query 'The Collection Date is prior to the System Screening Visit Date. Please review and reconcile.' (Site from System).		01 Sep 2020 14:57:07
User entered '28 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 14:57:07
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	01 Sep 2020 14:55:39
User opened query 'The Collection Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).		01 Sep 2020 14:55:39
User opened query 'The Collection Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	01 Sep 2020 14:55:39
User entered '27 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 14:55:39

**US3672377**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 20:00:36
User entered '13:00'	(b) (4), (b) (6)	01 Sep 2020 14:55:39

**US3672377**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User entered '28 Aug 2020 13:00'	System	01 Sep 2020 14:57:07
User entered '27 Aug 2020 13:00'	System	01 Sep 2020 14:55:39

US3672377

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 23:00:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 20:00:45
User closed query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	01 Sep 2020 14:59:41
Query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' answered by data change (Site from System).	System	01 Sep 2020 14:59:41
User entered '28 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Sep 2020 14:59:41
User opened query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	01 Sep 2020 14:59:30
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:59:30

**US3672377**

**Folder: Visit 1 Day 1**

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

**Generated On: 11 Aug 2021 23:00:38**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	01 Sep 2020 14:59:30



**US3672377**

**Folder: Visit 1 Day 1**

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

**Generated On: 11 Aug 2021 23:00:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 20:00:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 14:59:30

**US3672377**

**Folder: Visit 1 Day 1**

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

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 20:00:45
User entered '12:40'	(b) (4), (b) (6)	01 Sep 2020 14:59:30

**US3672377**

**Folder: Visit 1 Day 1**

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

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User entered '28 Aug 2020 12:40'	System	01 Sep 2020 14:59:41
User entered empty.	System	01 Sep 2020 14:59:30

**US3672377**

**Folder: Visit 1 Day 1**

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

**Generated On: 11 Aug 2021 23:00:38**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	01 Sep 2020 14:59:30

**US3672377**

**Folder: Visit 1 Day 1**

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

**Generated On: 11 Aug 2021 23:00:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 20:00:45
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 14:59:30

**US3672377**

**Folder: Visit 1 Day 1**

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

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 20:00:45
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 14:59:30

**US3672377**

**Folder: Visit 1 Day 1**

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

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User entered empty.	System	01 Sep 2020 14:59:30

**US3672377**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 20:00:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 14:59:59



**US3672377**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:57
User entered 'I'	System	01 Sep 2020 14:59:59

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
Data entry locked.	System	28 Aug 2020 17:51:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 17:51:22

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 23:00:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-28T13:56:05', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'cb913300-f7ae-476b-b400-3050a9fe5d94'	System	28 Aug 2020 17:57:28
User entered 'Yes (Y)'	System	28 Aug 2020 17:57:28

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 23:00:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-28T13:57:06', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'cb913300-f7ae-476b-b400-3050a9fe5d94'	System	28 Aug 2020 17:57:28
User entered '99.0'	System	28 Aug 2020 17:57:28

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-28T13:57:12', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'cb913300-f7ae-476b-b400-3050a9fe5d94'	System	28 Aug 2020 17:57:28
User entered 'Yes (Y)'	System	28 Aug 2020 17:57:28

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirm' (Site from System).	(b) (4), (b) (6)	24 Sep 2020 16:18:51
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	23 Sep 2020 18:42:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-28T13:57:18', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'cb913300-f7ae-476b-b400-3050a9fe5d94'	System	28 Aug 2020 17:57:28
User entered '1'	System	28 Aug 2020 17:57:28

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 23:00:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-28T13:57:18', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'cb913300-f7ae-476b-b400-3050a9fe5d94'	System	28 Aug 2020 17:57:28
User entered '0'	System	28 Aug 2020 17:57:28

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-28T13:57:24', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'cb913300-f7ae-476b-b400-3050a9fe5d94'	System	28 Aug 2020 17:57:28
User entered '28 Aug 2020 13:57'	System	28 Aug 2020 17:57:28



US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 23:00:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '28 Aug 2020 13:49'	System	28 Aug 2020 17:51:22

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '28 Aug 2020 16:19'	System	28 Aug 2020 17:51:22

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
Data entry locked.	System	28 Aug 2020 17:51:22
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 17:51:22

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 23:00:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-28T20:46:32', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'f737211b-9f1c-4fe9-93b1-6876902157fc'	System	29 Aug 2020 00:47:02
User entered 'Yes (Y)'	System	29 Aug 2020 00:47:02

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 23:00:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-28T20:46:36', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'f737211b-9f1c-4fe9-93b1-6876902157fc'	System	29 Aug 2020 00:47:02
User entered '98.9'	System	29 Aug 2020 00:47:02

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-28T20:46:40', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'f737211b-9f1c-4fe9-93b1-6876902157fc'	System	29 Aug 2020 00:47:02
User entered 'Yes (Y)'	System	29 Aug 2020 00:47:02

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirm' (Site from System).	(b) (4), (b) (6)	24 Sep 2020 16:16:40
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-28T20:46:47', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'f737211b-9f1c-4fe9-93b1-6876902157fc'	(b) (4), (b) (6)	23 Sep 2020 18:43:06
User entered '1'	System	29 Aug 2020 00:47:02
	System	29 Aug 2020 00:47:02
	System	29 Aug 2020 00:47:02

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 23:00:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-28T20:46:47', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'f737211b-9f1c-4fe9-93b1-6876902157fc'	System	29 Aug 2020 00:47:02
User entered '0'	System	29 Aug 2020 00:47:02



**US3672377**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-28T20:46:56', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'f737211b-9f1c-4fe9-93b1-6876902157fc'	System	29 Aug 2020 00:47:02
User entered '28 Aug 2020 20:46'	System	29 Aug 2020 00:47:02

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 23:00:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '28 Aug 2020 17:14'	System	28 Aug 2020 17:51:22

**US3672377**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 17:51:22

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
Data entry locked.	System	28 Aug 2020 17:51:22
User entered 'Day 2'	System	28 Aug 2020 17:51:22

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 23:00:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-29T21:36:52', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '5b667a3f-ae3d-4875-8069-6e736f793134'	System	30 Aug 2020 01:37:30
User entered 'Yes (Y)'	System	30 Aug 2020 01:37:30

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 23:00:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-29T21:36:55', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '5b667a3f-ae3d-4875-8069-6e736f793134'	System	30 Aug 2020 01:37:30
User entered '98.9'	System	30 Aug 2020 01:37:30

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-29T21:37:08', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '5b667a3f-ae3d-4875-8069-6e736f793134'	System	30 Aug 2020 01:37:30
User entered 'Yes (Y)'	System	30 Aug 2020 01:37:30

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirm' (Site from System).	(b) (4), (b) (6)	24 Sep 2020 16:17:24
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-29T21:37:23', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '5b667a3f-ae3d-4875-8069-6e736f793134'	System	30 Aug 2020 01:37:30
User entered '1'	System	30 Aug 2020 01:37:30



US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 23:00:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-29T21:37:23', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '5b667a3f-ae3d-4875-8069-6e736f793134'	System	30 Aug 2020 01:37:30
User entered '0'	System	30 Aug 2020 01:37:30

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-29T21:37:27', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '5b667a3f-ae3d-4875-8069-6e736f793134'	System	30 Aug 2020 01:37:30
User entered '29 Aug 2020 21:37'	System	30 Aug 2020 01:37:30

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 23:00:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 17:51:22

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 17:51:22

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
Data entry locked.	System	28 Aug 2020 17:51:22
User entered 'Day 3'	System	28 Aug 2020 17:51:22

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 23:00:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-31T07:21:51', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '0ae1cec5-99da-4093-a7f1-861ef304f0cf'	System	31 Aug 2020 11:22:07
User entered 'Yes (Y)'	System	31 Aug 2020 11:22:07

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 23:00:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-31T07:21:54', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '0ae1cec5-99da-4093-a7f1-861ef304f0cf'	System	31 Aug 2020 11:22:07
User entered '99.3'	System	31 Aug 2020 11:22:07

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-31T07:21:56', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '0ae1cec5-99da-4093-a7f1-861ef304f0cf'	System	31 Aug 2020 11:22:07
User entered 'Yes (Y)'	System	31 Aug 2020 11:22:07



US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirm' (Site from System).	(b) (4), (b) (6)	24 Sep 2020 16:17:55
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	23 Sep 2020 18:43:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-31T07:21:59', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '0ae1cec5-99da-4093-a7f1-861ef304f0cf'	System	31 Aug 2020 11:22:07
User entered '1'	System	31 Aug 2020 11:22:07

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 23:00:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-31T07:21:59', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '0ae1cec5-99da-4093-a7f1-861ef304f0cf' User entered '0'	System	31 Aug 2020 11:22:07
	System	31 Aug 2020 11:22:07

**US3672377**

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

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-31T07:22:01', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '0ae1cec5-99da-4093-a7f1-861ef304f0cf'	System	31 Aug 2020 11:22:07
User entered '31 Aug 2020 07:22'	System	31 Aug 2020 11:22:07

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 23:00:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 17:51:22

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 23:00:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 17:51:22

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
Data entry locked.	System	28 Aug 2020 17:51:22
User entered 'Day 4'	System	28 Aug 2020 17:51:22

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 23:00:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-31T23:19:15', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '50d0a5df-3646-4158-a9b9-15770f399cb7'	System	01 Sep 2020 03:19:29
User entered 'Yes (Y)'	System	01 Sep 2020 03:19:29

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 23:00:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-31T23:19:18', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '50d0a5df-3646-4158-a9b9-15770f399cb7' User entered '98.2'	System	01 Sep 2020 03:19:29
	System	01 Sep 2020 03:19:29



US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-31T23:19:20', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '50d0a5df-3646-4158-a9b9-15770f399cb7'	System	01 Sep 2020 03:19:29
User entered 'Yes (Y)'	System	01 Sep 2020 03:19:29

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirm' (Site from System).	(b) (4), (b) (6)	24 Sep 2020 16:20:12
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-31T23:19:22', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '50d0a5df-3646-4158-a9b9-15770f399cb7'	(b) (4), (b) (6)	23 Sep 2020 18:43:23
User entered '1'	System	01 Sep 2020 03:19:29
	System	01 Sep 2020 03:19:29
	System	01 Sep 2020 03:19:29

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 23:00:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-31T23:19:22', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '50d0a5df-3646-4158-a9b9-15770f399cb7' User entered '0'	System	01 Sep 2020 03:19:29
	System	01 Sep 2020 03:19:29

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-31T23:19:25', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '50d0a5df-3646-4158-a9b9-15770f399cb7'	System	01 Sep 2020 03:19:29
User entered '31 Aug 2020 23:19'	System	01 Sep 2020 03:19:29

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 23:00:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 17:51:22

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 17:51:22

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
Data entry locked.	System	28 Aug 2020 17:51:22
User entered 'Day 5'	System	28 Aug 2020 17:51:22

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 23:00:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-02T00:15:20', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'fd290760-c5e2-42ed-9f2d-139f6b4755f0'	System	02 Sep 2020 04:15:33
User entered 'Yes (Y)'	System	02 Sep 2020 04:15:33



US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 23:00:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-02T00:15:23', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'fd290760-c5e2-42ed-9f2d-139f6b4755f0'	System	02 Sep 2020 04:15:33
User entered '99.7'	System	02 Sep 2020 04:15:33

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-02T00:15:25', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'fd290760-c5e2-42ed-9f2d-139f6b4755f0'	System	02 Sep 2020 04:15:33
User entered 'Yes (Y)'	System	02 Sep 2020 04:15:33

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirm' (Site from System).	(b) (4), (b) (6)	24 Sep 2020 16:20:27
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	23 Sep 2020 18:43:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-02T00:15:27', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'fd290760-c5e2-42ed-9f2d-139f6b4755f0'	System	02 Sep 2020 04:15:33
User entered '1'	System	02 Sep 2020 04:15:33

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 23:00:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-02T00:15:27', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'fd290760-c5e2-42ed-9f2d-139f6b4755f0'	System	02 Sep 2020 04:15:33
User entered '0'	System	02 Sep 2020 04:15:33

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-02T00:15:30', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'fd290760-c5e2-42ed-9f2d-139f6b4755f0'	System	02 Sep 2020 04:15:33
User entered '02 Sep 2020 00:15'	System	02 Sep 2020 04:15:33

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 23:00:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 17:51:22

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 17:51:22

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
Data entry locked.	System	28 Aug 2020 17:51:22
User entered 'Day 6'	System	28 Aug 2020 17:51:22



US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 23:00:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-03T06:43:33', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'c9256eac-4f04-4ca3-bec3-605bae7e58d0'	System	03 Sep 2020 10:43:42
User entered 'Yes (Y)'	System	03 Sep 2020 10:43:42

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 23:00:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-03T06:43:36', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'c9256eac-4f04-4ca3-bec3-605bae7e58d0'	System	03 Sep 2020 10:43:42
User entered '99.2'	System	03 Sep 2020 10:43:42

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-03T06:43:38', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'c9256eac-4f04-4ca3-bec3-605bae7e58d0'	System	03 Sep 2020 10:43:42
User entered 'Yes (Y)'	System	03 Sep 2020 10:43:42

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirm' (Site from System).	(b) (4), (b) (6)	24 Sep 2020 16:20:43
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-03T06:43:39', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'c9256eac-4f04-4ca3-bec3-605bae7e58d0'	(b) (4), (b) (6)	23 Sep 2020 18:43:32
User entered '1'	System	03 Sep 2020 10:43:42
	System	03 Sep 2020 10:43:42
	System	03 Sep 2020 10:43:42

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 23:00:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-03T06:43:39', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'c9256eac-4f04-4ca3-bec3-605bae7e58d0'	System	03 Sep 2020 10:43:42
User entered '0'	System	03 Sep 2020 10:43:42

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-03T06:43:41', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'c9256eac-4f04-4ca3-bec3-605bae7e58d0'	System	03 Sep 2020 10:43:42
User entered '03 Sep 2020 06:43'	System	03 Sep 2020 10:43:42

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 23:00:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 17:51:22

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 17:51:22



US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
Data entry locked.	System	28 Aug 2020 17:51:22
User entered 'Day 7'	System	28 Aug 2020 17:51:22

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 23:00:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-04T00:37:05', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'e1f16ac1-2a87-4ba4-82d4-f9d7a2495301'	System	04 Sep 2020 04:37:17
User entered 'Yes (Y)'	System	04 Sep 2020 04:37:17

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 23:00:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-04T00:37:08', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'e1f16ac1-2a87-4ba4-82d4-f9d7a2495301'	System	04 Sep 2020 04:37:17
User entered '99.6'	System	04 Sep 2020 04:37:17

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-04T00:37:10', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'e1f16ac1-2a87-4ba4-82d4-f9d7a2495301'	System	04 Sep 2020 04:37:17
User entered 'Yes (Y)'	System	04 Sep 2020 04:37:17

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirm' (Site from System).	(b) (4), (b) (6)	24 Sep 2020 16:19:17
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-04T00:37:12', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'e1f16ac1-2a87-4ba4-82d4-f9d7a2495301'	(b) (4), (b) (6)	23 Sep 2020 18:43:37
User entered '1'	System	04 Sep 2020 04:37:17
	System	04 Sep 2020 04:37:17
	System	04 Sep 2020 04:37:17

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 23:00:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-04T00:37:12', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'e1f16ac1-2a87-4ba4-82d4-f9d7a2495301' User entered '0'	System	04 Sep 2020 04:37:17
	System	04 Sep 2020 04:37:17

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-04T00:37:14', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'e1f16ac1-2a87-4ba4-82d4-f9d7a2495301'	System	04 Sep 2020 04:37:17
User entered '04 Sep 2020 00:37'	System	04 Sep 2020 04:37:17

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 17:51:22



**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 17:51:22

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
Data entry locked.	System	03 Sep 2020 10:43:42
User entered 'Day 8'	System	03 Sep 2020 10:43:42

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 23:00:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-05T08:21:01', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'f4ed017f-9bd3-41d3-969d-8e1261ed9683'	System	05 Sep 2020 12:21:10
User entered 'Yes (Y)'	System	05 Sep 2020 12:21:10

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 23:00:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-05T08:21:03', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'f4ed017f-9bd3-41d3-969d-8e1261ed9683'	System	05 Sep 2020 12:21:10
User entered '98.9'	System	05 Sep 2020 12:21:10

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-05T08:21:05', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'f4ed017f-9bd3-41d3-969d-8e1261ed9683'	System	05 Sep 2020 12:21:10
User entered 'Yes (Y)'	System	05 Sep 2020 12:21:10

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirm' (Site from System).	(b) (4), (b) (6)	24 Sep 2020 16:19:50
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	23 Sep 2020 18:43:42
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-05T08:21:06', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'f4ed017f-9bd3-41d3-969d-8e1261ed9683'	System	05 Sep 2020 12:21:10
User entered '1'	System	05 Sep 2020 12:21:10

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 11 Aug 2021 23:00:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-05T08:21:06', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'f4ed017f-9bd3-41d3-969d-8e1261ed9683'	System	05 Sep 2020 12:21:10
User entered '0'	System	05 Sep 2020 12:21:10

**US3672377**

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

**Form: Temperature\_Day(8)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-05T08:21:08', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'f4ed017f-9bd3-41d3-969d-8e1261ed9683'	System	05 Sep 2020 12:21:10
User entered '05 Sep 2020 08:21'	System	05 Sep 2020 12:21:10



**US3672377**

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

**Form: Temperature\_Day(8)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 10:43:42

**US3672377**

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

**Form: Temperature\_Day(8)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 10:43:42

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
Data entry locked.	System	04 Sep 2020 04:37:17
User entered 'Day 9'	System	04 Sep 2020 04:37:17

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 11 Aug 2021 23:00:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-05T23:59:59', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '3f29b76f-7d49-4ab2-968b-89d4c011b123'	System	06 Sep 2020 04:00:15
User entered 'Yes (Y)'	System	06 Sep 2020 04:00:15

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 11 Aug 2021 23:00:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-06T00:00:03', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '3f29b76f-7d49-4ab2-968b-89d4c011b123'	System	06 Sep 2020 04:00:15
User entered '98.4'	System	06 Sep 2020 04:00:15

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-06T00:00:05', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '3f29b76f-7d49-4ab2-968b-89d4c011b123'	System	06 Sep 2020 04:00:15
User entered 'Yes (Y)'	System	06 Sep 2020 04:00:15

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirm' (Site from System).	(b) (4), (b) (6)	24 Sep 2020 16:19:34
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-06T00:00:07', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '3f29b76f-7d49-4ab2-968b-89d4c011b123'	(b) (4), (b) (6)	23 Sep 2020 18:43:47
User entered '1'	System	06 Sep 2020 04:00:15
	System	06 Sep 2020 04:00:15
	System	06 Sep 2020 04:00:15

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 11 Aug 2021 23:00:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-06T00:00:07', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '3f29b76f-7d49-4ab2-968b-89d4c011b123'	System	06 Sep 2020 04:00:15
User entered '0'	System	06 Sep 2020 04:00:15



**US3672377**

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

**Form: Temperature\_Day(9)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-06T00:00:09', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '3f29b76f-7d49-4ab2-968b-89d4c011b123'	System	06 Sep 2020 04:00:15
User entered '06 Sep 2020 00:00'	System	06 Sep 2020 04:00:15

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 11 Aug 2021 23:00:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 04:37:17

**US3672377**

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

**Form: Temperature\_Day(9)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 04:37:17

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
Data entry locked.	System	05 Sep 2020 12:21:10
User entered 'Day 10'	System	05 Sep 2020 12:21:10

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 11 Aug 2021 23:00:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-07T00:28:06', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '69a2b1c9-5109-4580-a3a8-efa08338e811'	System	07 Sep 2020 04:28:18
User entered 'Yes (Y)'	System	07 Sep 2020 04:28:18

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 11 Aug 2021 23:00:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-07T00:28:10', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '69a2b1c9-5109-4580-a3a8-efa08338e811'	System	07 Sep 2020 04:28:18
User entered '99.3'	System	07 Sep 2020 04:28:18

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-07T00:28:13', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '69a2b1c9-5109-4580-a3a8-efa08338e811'	System	07 Sep 2020 04:28:18
User entered 'No (N)'	System	07 Sep 2020 04:28:18

**US3672377**

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

**Form: Temperature\_Day(10)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-07T00:28:15', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '69a2b1c9-5109-4580-a3a8-efa08338e811'	System	07 Sep 2020 04:28:18
User entered '07 Sep 2020 00:28'	System	07 Sep 2020 04:28:18



US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 11 Aug 2021 23:00:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 12:21:10

US3672377

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 11 Aug 2021 23:00:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 12:21:10

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
Data entry locked.	System	28 Aug 2020 17:51:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 17:51:22

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:00:38

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 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-28T13:57:34', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'bbbb2130-70e1-4014-8185-a041e27c4940'	System	28 Aug 2020 17:58:46
User entered 'Does not interfere with activity (2)'	System	28 Aug 2020 17:58:46

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:00:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-28T13:57:41', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'bbbb2130-70e1-4014-8185-a041e27c4940'	System	28 Aug 2020 17:58:46
User entered 'Yes (Y)'	System	28 Aug 2020 17:58:46

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:00:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-28T13:58:20', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'bbbb2130-70e1-4014-8185-a041e27c4940'	System	28 Aug 2020 17:58:46
User entered '50'	System	28 Aug 2020 17:58:46

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-28T13:58:33', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'bbbb2130-70e1-4014-8185-a041e27c4940'	System	28 Aug 2020 17:58:46
User entered 'No (N)'	System	28 Aug 2020 17:58:46

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 23:00:38

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 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-28T13:58:38', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'bbbb2130-70e1-4014-8185-a041e27c4940'	System	28 Aug 2020 17:58:46
User entered 'None (1)'	System	28 Aug 2020 17:58:46



**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-28T13:58:40', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'bbbb2130-70e1-4014-8185-a041e27c4940'	System	28 Aug 2020 17:58:46
User entered '28 Aug 2020 13:58'	System	28 Aug 2020 17:58:46

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '28 Aug 2020 13:49'	System	28 Aug 2020 17:51:22

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '28 Aug 2020 16:19'	System	28 Aug 2020 17:51:22

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
Data entry locked.	System	28 Aug 2020 17:51:22
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 17:51:22

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:00:38

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 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-28T20:47:32', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '9402b1eb-49b5-494a-bc8f-f387babe2b63'	System	29 Aug 2020 00:48:11
User entered 'Does not interfere with activity (2)'	System	29 Aug 2020 00:48:11

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:00:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-28T20:47:40', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '9402b1eb-49b5-494a-bc8f-f387babe2b63'	System	29 Aug 2020 00:48:11
User entered 'Yes (Y)'	System	29 Aug 2020 00:48:11

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:00:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-28T20:47:44', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '9402b1eb-49b5-494a-bc8f-f387babe2b63'	System	29 Aug 2020 00:48:11
User entered '10'	System	29 Aug 2020 00:48:11

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-28T20:47:54', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '9402b1eb-49b5-494a-bc8f-f387babe2b63'	System	29 Aug 2020 00:48:11
User entered 'No (N)'	System	29 Aug 2020 00:48:11



US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:00:38

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 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-28T20:48:06', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '9402b1eb-49b5-494a-bc8f-f387babe2b63'	System	29 Aug 2020 00:48:11
User entered 'None (1)'	System	29 Aug 2020 00:48:11

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 23:00:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-28T20:48:08', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '9402b1eb-49b5-494a-bc8f-f387babe2b63'	System	29 Aug 2020 00:48:11
User entered '28 Aug 2020 20:48'	System	29 Aug 2020 00:48:11

**US3672377**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '28 Aug 2020 17:14'	System	28 Aug 2020 17:51:22

**US3672377**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 17:51:22

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
Data entry locked.	System	28 Aug 2020 17:51:22
User entered 'Day 2'	System	28 Aug 2020 17:51:22

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:00:38

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 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-29T21:37:36', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'c915529a-e071-4afd-8c16-b671b366f6e4'	System	30 Aug 2020 01:38:57
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	30 Aug 2020 01:38:57

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:00:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-29T21:37:44', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'c915529a-e071-4afd-8c16-b671b366f6e4'	System	30 Aug 2020 01:38:57
User entered 'No (N)'	System	30 Aug 2020 01:38:57

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-29T21:38:00', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'c915529a-e071-4afd-8c16-b671b366f6e4'	System	30 Aug 2020 01:38:57
User entered 'Yes (Y)'	System	30 Aug 2020 01:38:57



US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:00:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-29T21:38:28', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'c915529a-e071-4afd-8c16-b671b366f6e4'	System	30 Aug 2020 01:38:57
User entered '60'	System	30 Aug 2020 01:38:57

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:00:38

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 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-29T21:38:47', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'c915529a-e071-4afd-8c16-b671b366f6e4'	System	30 Aug 2020 01:38:57
User entered 'None (1)'	System	30 Aug 2020 01:38:57

**US3672377**

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

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-29T21:38:55', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'c915529a-e071-4afd-8c16-b671b366f6e4'	System	30 Aug 2020 01:38:57
User entered '29 Aug 2020 21:38'	System	30 Aug 2020 01:38:57

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 23:00:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 17:51:22

**US3672377**

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

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 17:51:22

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
Data entry locked.	System	28 Aug 2020 17:51:22
User entered 'Day 3'	System	28 Aug 2020 17:51:22

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:00:38

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 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-31T07:22:04', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '7b45773c-391f-44dc-9141-fd9f6c58067f'	System	31 Aug 2020 11:22:29
User entered 'None (1)'	System	31 Aug 2020 11:22:29

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:00:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-31T07:22:06', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '7b45773c-391f-44dc-9141-fd9f6c58067f'	System	31 Aug 2020 11:22:29
User entered 'No (N)'	System	31 Aug 2020 11:22:29



US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-31T07:22:15', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '7b45773c-391f-44dc-9141-fd9f6c58067f'	System	31 Aug 2020 11:22:29
User entered 'Yes (Y)'	System	31 Aug 2020 11:22:29

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:00:38

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-31T07:22:20', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '7b45773c-391f-44dc-9141-fd9f6c58067f'	System	31 Aug 2020 11:22:29
User entered '30'	System	31 Aug 2020 11:22:29

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 23:00:38

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 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-31T07:22:22', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '7b45773c-391f-44dc-9141-fd9f6c58067f'	System	31 Aug 2020 11:22:29
User entered 'None (1)'	System	31 Aug 2020 11:22:29

**US3672377**

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

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-31T07:22:24', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '7b45773c-391f-44dc-9141-fd9f6c58067f'	System	31 Aug 2020 11:22:29
User entered '31 Aug 2020 07:22'	System	31 Aug 2020 11:22:29

**US3672377**

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

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 17:51:22

**US3672377**

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

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 17:51:22

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
Data entry locked.	System	28 Aug 2020 17:51:22
User entered 'Day 4'	System	28 Aug 2020 17:51:22

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:00:38

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 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-31T23:19:28', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'e513f9f3-c6c7-4636-bd58-838a0e2e5648'	System	01 Sep 2020 03:19:39
User entered 'None (1)'	System	01 Sep 2020 03:19:39



US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:00:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-31T23:19:30', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'e513f9f3-c6c7-4636-bd58-838a0e2e5648'	System	01 Sep 2020 03:19:39
User entered 'No (N)'	System	01 Sep 2020 03:19:39

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-31T23:19:32', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'e513f9f3-c6c7-4636-bd58-838a0e2e5648'	System	01 Sep 2020 03:19:39
User entered 'No (N)'	System	01 Sep 2020 03:19:39

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 23:00:38

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 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-31T23:19:34', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'e513f9f3-c6c7-4636-bd58-838a0e2e5648'	System	01 Sep 2020 03:19:39
User entered 'None (1)'	System	01 Sep 2020 03:19:39

**US3672377**

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

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-31T23:19:37', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'e513f9f3-c6c7-4636-bd58-838a0e2e5648'	System	01 Sep 2020 03:19:39
User entered '31 Aug 2020 23:19'	System	01 Sep 2020 03:19:39

**US3672377**

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

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 17:51:22

**US3672377**

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

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 17:51:22

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
Data entry locked.	System	28 Aug 2020 17:51:22
User entered 'Day 5'	System	28 Aug 2020 17:51:22

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:00:38

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 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-02T00:15:32', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'cb6561ab-c3a5-4644-b78d-60c54c94a5cb'	System	02 Sep 2020 04:15:45
User entered 'None (1)'	System	02 Sep 2020 04:15:45



US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:00:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-02T00:15:34', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'cb6561ab-c3a5-4644-b78d-60c54c94a5cb'	System	02 Sep 2020 04:15:45
User entered 'No (N)'	System	02 Sep 2020 04:15:45

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-02T00:15:35', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'cb6561ab-c3a5-4644-b78d-60c54c94a5cb'	System	02 Sep 2020 04:15:45
User entered 'No (N)'	System	02 Sep 2020 04:15:45

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:00:38

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 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-02T00:15:37', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'cb6561ab-c3a5-4644-b78d-60c54c94a5cb'	System	02 Sep 2020 04:15:45
User entered 'None (1)'	System	02 Sep 2020 04:15:45

**US3672377**

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

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-02T00:15:40', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'cb6561ab-c3a5-4644-b78d-60c54c94a5cb'	System	02 Sep 2020 04:15:45
User entered '02 Sep 2020 00:15'	System	02 Sep 2020 04:15:45

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 23:00:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 17:51:22

**US3672377**

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

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 17:51:22

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
Data entry locked.	System	28 Aug 2020 17:51:22
User entered 'Day 6'	System	28 Aug 2020 17:51:22

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:00:38

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 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-03T06:43:44', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '76fd345c-9bc4-4b7d-a53f-6837ea0dc375'	System	03 Sep 2020 10:43:53
User entered 'None (1)'	System	03 Sep 2020 10:43:53



US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:00:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-03T06:43:46', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '76fd345c-9bc4-4b7d-a53f-6837ea0dc375'	System	03 Sep 2020 10:43:53
User entered 'No (N)'	System	03 Sep 2020 10:43:53

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-03T06:43:48', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '76fd345c-9bc4-4b7d-a53f-6837ea0dc375'	System	03 Sep 2020 10:43:53
User entered 'No (N)'	System	03 Sep 2020 10:43:53

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:00:38

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 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-03T06:43:49', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '76fd345c-9bc4-4b7d-a53f-6837ea0dc375'	System	03 Sep 2020 10:43:53
User entered 'None (1)'	System	03 Sep 2020 10:43:53

**US3672377**

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

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-03T06:43:51', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '76fd345c-9bc4-4b7d-a53f-6837ea0dc375'	System	03 Sep 2020 10:43:53
User entered '03 Sep 2020 06:43'	System	03 Sep 2020 10:43:53

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 23:00:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 17:51:22

**US3672377**

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

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 17:51:22

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
Data entry locked.	System	28 Aug 2020 17:51:22
User entered 'Day 7'	System	28 Aug 2020 17:51:22

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:00:38

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 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-04T00:37:17', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '843bc80a-3d9c-481d-9ae9-4e2e9a6220d1'	System	04 Sep 2020 04:37:28
User entered 'None (1)'	System	04 Sep 2020 04:37:28



US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:00:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-04T00:37:20', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '843bc80a-3d9c-481d-9ae9-4e2e9a6220d1'	System	04 Sep 2020 04:37:28
User entered 'No (N)'	System	04 Sep 2020 04:37:28

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-04T00:37:21', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '843bc80a-3d9c-481d-9ae9-4e2e9a6220d1'	System	04 Sep 2020 04:37:28
User entered 'No (N)'	System	04 Sep 2020 04:37:28

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:00:38

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 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-04T00:37:23', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '843bc80a-3d9c-481d-9ae9-4e2e9a6220d1'	System	04 Sep 2020 04:37:28
User entered 'None (1)'	System	04 Sep 2020 04:37:28

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:00:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-04T00:37:25', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '843bc80a-3d9c-481d-9ae9-4e2e9a6220d1'	System	04 Sep 2020 04:37:28
User entered '04 Sep 2020 00:37'	System	04 Sep 2020 04:37:28

US3672377

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 23:00:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 17:51:22

**US3672377**

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

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 17:51:22

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
Data entry locked.	System	28 Aug 2020 17:51:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 17:51:22

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-28T13:58:47', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '51981f37-0147-48d4-9832-8bdc329b49b'	System	28 Aug 2020 17:59:08
User entered 'None (0)'	System	28 Aug 2020 17:59:08



US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:00:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-28T13:58:49', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '51981f37-0147-48d4-9832-8bdc329b49b'	System	28 Aug 2020 17:59:08
User entered 'None (0)'	System	28 Aug 2020 17:59:08

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:00:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-28T13:58:52', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '51981f37-0147-48d4-9832-8bdc329b49b'	System	28 Aug 2020 17:59:08
User entered 'None (0)'	System	28 Aug 2020 17:59:08

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:00:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-28T13:58:53', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '51981f37-0147-48d4-9832-8bdc329b49b'	System	28 Aug 2020 17:59:08
User entered 'None (0)'	System	28 Aug 2020 17:59:08

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-28T13:58:55', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '51981f37-0147-48d4-9832-8bdc329b49b'	System	28 Aug 2020 17:59:08
User entered 'None (0)'	System	28 Aug 2020 17:59:08

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-28T13:58:56', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '51981f37-0147-48d4-9832-8bdc329b49b'	System	28 Aug 2020 17:59:08
User entered 'None (0)'	System	28 Aug 2020 17:59:08

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 23:00:38

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 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-28T13:59:02', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '51981f37-0147-48d4-9832-8bdc329b49b'	System	28 Aug 2020 17:59:08
User entered 'No (N)'	System	28 Aug 2020 17:59:08

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-28T13:59:04', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '51981f37-0147-48d4-9832-8bdc329b49b'	System	28 Aug 2020 17:59:08
User entered '28 Aug 2020 13:59'	System	28 Aug 2020 17:59:08

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '28 Aug 2020 13:49'	System	28 Aug 2020 17:51:22



**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '28 Aug 2020 16:19'	System	28 Aug 2020 17:51:22

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
Data entry locked.	System	28 Aug 2020 17:51:22
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 17:51:22

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:00:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-28T20:48:17', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '84bc582e-fdb5-4470-9d7e-bcf7b0e0a5cb'	System	29 Aug 2020 00:48:51
User entered 'No interference with activity (1)'	System	29 Aug 2020 00:48:51

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:00:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-28T20:48:25', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '84bc582e-fdb5-4470-9d7e-bcf7b0e0a5cb'	System	29 Aug 2020 00:48:51
User entered 'None (0)'	System	29 Aug 2020 00:48:51

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:00:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-28T20:48:28', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '84bc582e-fdb5-4470-9d7e-bcf7b0e0a5cb'	System	29 Aug 2020 00:48:51
User entered 'None (0)'	System	29 Aug 2020 00:48:51

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:00:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-28T20:48:31', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '84bc582e-fdb5-4470-9d7e-bcf7b0e0a5cb'	System	29 Aug 2020 00:48:51
User entered 'None (0)'	System	29 Aug 2020 00:48:51

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:00:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-28T20:48:34', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '84bc582e-fdb5-4470-9d7e-bcf7b0e0a5cb'	System	29 Aug 2020 00:48:51
User entered 'None (0)'	System	29 Aug 2020 00:48:51

**US3672377**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:00:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-28T20:48:37', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '84bc582e-fdb5-4470-9d7e-bcf7b0e0a5cb'	System	29 Aug 2020 00:48:51
User entered 'None (0)'	System	29 Aug 2020 00:48:51



US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 23:00:38

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 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-28T20:48:45', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '84bc582e-fdb5-4470-9d7e-bcf7b0e0a5cb'	System	29 Aug 2020 00:48:51
User entered 'No (N)'	System	29 Aug 2020 00:48:51

**US3672377**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-28T20:48:47', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '84bc582e-fdb5-4470-9d7e-bcf7b0e0a5cb'	System	29 Aug 2020 00:48:51
User entered '28 Aug 2020 20:48'	System	29 Aug 2020 00:48:51

**US3672377**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '28 Aug 2020 17:14'	System	28 Aug 2020 17:51:22

**US3672377**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 17:51:22

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
Data entry locked.	System	28 Aug 2020 17:51:22
User entered 'Day 2'	System	28 Aug 2020 17:51:22

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-29T21:39:02', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '8f4b207d-cc32-4496-9ec5-0f5e4df201cb'	System	30 Aug 2020 01:39:18
User entered 'No interference with activity (1)'	System	30 Aug 2020 01:39:18

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 23:00:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-29T21:39:05', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '8f4b207d-cc32-4496-9ec5-0f5e4df201cb'	System	30 Aug 2020 01:39:18
User entered 'None (0)'	System	30 Aug 2020 01:39:18

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 23:00:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-29T21:39:08', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '8f4b207d-cc32-4496-9ec5-0f5e4df201cb'	System	30 Aug 2020 01:39:18
User entered 'None (0)'	System	30 Aug 2020 01:39:18



US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 23:00:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-29T21:39:10', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '8f4b207d-cc32-4496-9ec5-0f5e4df201cb'	System	30 Aug 2020 01:39:18
User entered 'None (0)'	System	30 Aug 2020 01:39:18

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-29T21:39:11', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '8f4b207d-cc32-4496-9ec5-0f5e4df201cb'	System	30 Aug 2020 01:39:18
User entered 'None (0)'	System	30 Aug 2020 01:39:18

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-29T21:39:13', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '8f4b207d-cc32-4496-9ec5-0f5e4df201cb'	System	30 Aug 2020 01:39:18
User entered 'None (0)'	System	30 Aug 2020 01:39:18

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 23:00:38

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 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-29T21:39:15', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '8f4b207d-cc32-4496-9ec5-0f5e4df201cb'	System	30 Aug 2020 01:39:18
User entered 'No (N)'	System	30 Aug 2020 01:39:18

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-29T21:39:17', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '8f4b207d-cc32-4496-9ec5-0f5e4df201cb'	System	30 Aug 2020 01:39:18
User entered '29 Aug 2020 21:39'	System	30 Aug 2020 01:39:18

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 17:51:22

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 17:51:22

**US3672377**

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

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
Data entry locked.	System	28 Aug 2020 17:51:22
User entered 'Day 3'	System	28 Aug 2020 17:51:22



**US3672377**

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

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 23:00:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-31T07:22:29', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '68e767ca-04c8-4c67-8405-66b69f5ed009'	System	31 Aug 2020 11:22:41
User entered 'No interference with activity (1)'	System	31 Aug 2020 11:22:41

**US3672377**

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

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 23:00:38**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-31T07:22:30', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '68e767ca-04c8-4c67-8405-66b69f5ed009'	System	31 Aug 2020 11:22:41
User entered 'None (0)'	System	31 Aug 2020 11:22:41

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 23:00:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-31T07:22:31', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '68e767ca-04c8-4c67-8405-66b69f5ed009'	System	31 Aug 2020 11:22:41
User entered 'None (0)'	System	31 Aug 2020 11:22:41

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 23:00:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-31T07:22:32', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '68e767ca-04c8-4c67-8405-66b69f5ed009'	System	31 Aug 2020 11:22:41
User entered 'None (0)'	System	31 Aug 2020 11:22:41

**US3672377**

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

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 23:00:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-31T07:22:33', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '68e767ca-04c8-4c67-8405-66b69f5ed009'	System	31 Aug 2020 11:22:41
User entered 'None (0)'	System	31 Aug 2020 11:22:41

**US3672377**

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

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 23:00:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-31T07:22:34', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '68e767ca-04c8-4c67-8405-66b69f5ed009'	System	31 Aug 2020 11:22:41
User entered 'None (0)'	System	31 Aug 2020 11:22:41

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 23:00:38

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 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-31T07:22:36', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '68e767ca-04c8-4c67-8405-66b69f5ed009'	System	31 Aug 2020 11:22:41
User entered 'No (N)'	System	31 Aug 2020 11:22:41

**US3672377**

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

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-31T07:22:38', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '68e767ca-04c8-4c67-8405-66b69f5ed009'	System	31 Aug 2020 11:22:41
User entered '31 Aug 2020 07:22'	System	31 Aug 2020 11:22:41



**US3672377**

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

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 17:51:22

**US3672377**

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

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 17:51:22

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
Data entry locked.	System	28 Aug 2020 17:51:22
User entered 'Day 4'	System	28 Aug 2020 17:51:22

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-31T23:19:40', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'a9c1dc4c-06f4-41bf-b96c-eba8209b08d2'	System	01 Sep 2020 03:19:55
User entered 'No interference with activity (1)'	System	01 Sep 2020 03:19:55

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 23:00:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-31T23:19:42', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'a9c1dc4c-06f4-41bf-b96c-eba8209b08d2'	System	01 Sep 2020 03:19:55
User entered 'None (0)'	System	01 Sep 2020 03:19:55

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 23:00:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-31T23:19:43', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'a9c1dc4c-06f4-41bf-b96c-eba8209b08d2'	System	01 Sep 2020 03:19:55
User entered 'None (0)'	System	01 Sep 2020 03:19:55

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 23:00:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-31T23:19:45', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'a9c1dc4c-06f4-41bf-b96c-eba8209b08d2'	System	01 Sep 2020 03:19:55
User entered 'None (0)'	System	01 Sep 2020 03:19:55

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 23:00:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-31T23:19:46', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'a9c1dc4c-06f4-41bf-b96c-eba8209b08d2'	System	01 Sep 2020 03:19:55
User entered 'None (0)'	System	01 Sep 2020 03:19:55



**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-31T23:19:47', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'a9c1dc4c-06f4-41bf-b96c-eba8209b08d2'	System	01 Sep 2020 03:19:55
User entered 'None (0)'	System	01 Sep 2020 03:19:55

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 23:00:38

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 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-31T23:19:49', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'a9c1dc4c-06f4-41bf-b96c-eba8209b08d2'	System	01 Sep 2020 03:19:55
User entered 'No (N)'	System	01 Sep 2020 03:19:55

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-08-31T23:19:51', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'a9c1dc4c-06f4-41bf-b96c-eba8209b08d2'	System	01 Sep 2020 03:19:55
User entered '31 Aug 2020 23:19'	System	01 Sep 2020 03:19:55

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 17:51:22

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 17:51:22

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
Data entry locked.	System	28 Aug 2020 17:51:22
User entered 'Day 5'	System	28 Aug 2020 17:51:22

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-02T00:15:43', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'd039c44b-5843-4e06-a195-606a18a79e3e'	System	02 Sep 2020 04:15:54
User entered 'No interference with activity (1)'	System	02 Sep 2020 04:15:54

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 23:00:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-02T00:15:45', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'd039c44b-5843-4e06-a195-606a18a79e3e'	System	02 Sep 2020 04:15:54
User entered 'None (0)'	System	02 Sep 2020 04:15:54



US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 23:00:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-02T00:15:46', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'd039c44b-5843-4e06-a195-606a18a79e3e'	System	02 Sep 2020 04:15:54
User entered 'None (0)'	System	02 Sep 2020 04:15:54

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 23:00:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-02T00:15:47', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'd039c44b-5843-4e06-a195-606a18a79e3e'	System	02 Sep 2020 04:15:54
User entered 'None (0)'	System	02 Sep 2020 04:15:54

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 23:00:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-02T00:15:48', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'd039c44b-5843-4e06-a195-606a18a79e3e'	System	02 Sep 2020 04:15:54
User entered 'None (0)'	System	02 Sep 2020 04:15:54

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-02T00:15:49', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'd039c44b-5843-4e06-a195-606a18a79e3e'	System	02 Sep 2020 04:15:54
User entered 'None (0)'	System	02 Sep 2020 04:15:54

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 23:00:38

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 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-02T00:15:51', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'd039c44b-5843-4e06-a195-606a18a79e3e'	System	02 Sep 2020 04:15:54
User entered 'No (N)'	System	02 Sep 2020 04:15:54

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-02T00:15:53', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'd039c44b-5843-4e06-a195-606a18a79e3e'	System	02 Sep 2020 04:15:54
User entered '02 Sep 2020 00:15'	System	02 Sep 2020 04:15:54

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 17:51:22

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 17:51:22



US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
Data entry locked.	System	28 Aug 2020 17:51:22
User entered 'Day 6'	System	28 Aug 2020 17:51:22

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 23:00:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-03T06:43:55', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'c70857d8-238c-48ec-bd97-bdff9d5a69cf'	System	03 Sep 2020 10:44:09
User entered 'No interference with activity (1)'	System	03 Sep 2020 10:44:09

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 23:00:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-03T06:43:56', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'c70857d8-238c-48ec-bd97-bdff9d5a69cf'	System	03 Sep 2020 10:44:09
User entered 'None (0)'	System	03 Sep 2020 10:44:09

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 23:00:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-03T06:43:59', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'c70857d8-238c-48ec-bd97-bdff9d5a69cf'	System	03 Sep 2020 10:44:09
User entered 'None (0)'	System	03 Sep 2020 10:44:09

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 23:00:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-03T06:44:01', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'c70857d8-238c-48ec-bd97-bdff9d5a69cf'	System	03 Sep 2020 10:44:09
User entered 'None (0)'	System	03 Sep 2020 10:44:09

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 23:00:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-03T06:44:02', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'c70857d8-238c-48ec-bd97-bdff9d5a69cf'	System	03 Sep 2020 10:44:09
User entered 'None (0)'	System	03 Sep 2020 10:44:09

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 23:00:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-03T06:44:03', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'c70857d8-238c-48ec-bd97-bdff9d5a69cf'	System	03 Sep 2020 10:44:09
User entered 'None (0)'	System	03 Sep 2020 10:44:09

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 23:00:38

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 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-03T06:44:05', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'c70857d8-238c-48ec-bd97-bdff9d5a69cf'	System	03 Sep 2020 10:44:09
User entered 'No (N)'	System	03 Sep 2020 10:44:09



**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-03T06:44:07', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'c70857d8-238c-48ec-bd97-bdff9d5a69cf'	System	03 Sep 2020 10:44:09
User entered '03 Sep 2020 06:44'	System	03 Sep 2020 10:44:09

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 17:51:22

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 17:51:22

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
Data entry locked.	System	28 Aug 2020 17:51:22
User entered 'Day 7'	System	28 Aug 2020 17:51:22

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 23:00:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-04T00:37:30', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '77122ff2-681f-4715-b591-b86a3a087e9f'	System	04 Sep 2020 04:37:45
User entered 'No interference with activity (1)'	System	04 Sep 2020 04:37:45

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 23:00:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-04T00:37:31', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '77122ff2-681f-4715-b591-b86a3a087e9f'	System	04 Sep 2020 04:37:45
User entered 'None (0)'	System	04 Sep 2020 04:37:45

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 23:00:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-04T00:37:33', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '77122ff2-681f-4715-b591-b86a3a087e9f'	System	04 Sep 2020 04:37:45
User entered 'None (0)'	System	04 Sep 2020 04:37:45

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 23:00:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-04T00:37:34', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '77122ff2-681f-4715-b591-b86a3a087e9f'	System	04 Sep 2020 04:37:45
User entered 'None (0)'	System	04 Sep 2020 04:37:45



US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 23:00:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-04T00:37:36', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '77122ff2-681f-4715-b591-b86a3a087e9f'	System	04 Sep 2020 04:37:45
User entered 'None (0)'	System	04 Sep 2020 04:37:45

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 23:00:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-04T00:37:38', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '77122ff2-681f-4715-b591-b86a3a087e9f'	System	04 Sep 2020 04:37:45
User entered 'None (0)'	System	04 Sep 2020 04:37:45

US3672377

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 23:00:38

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 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-04T00:37:39', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '77122ff2-681f-4715-b591-b86a3a087e9f'	System	04 Sep 2020 04:37:45
User entered 'No (N)'	System	04 Sep 2020 04:37:45

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-04T00:37:42', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '77122ff2-681f-4715-b591-b86a3a087e9f'	System	04 Sep 2020 04:37:45
User entered '04 Sep 2020 00:37'	System	04 Sep 2020 04:37:45

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 17:51:22

**US3672377**

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

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

**Generated On: 11 Aug 2021 23:00:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 17:51:22

US3672377

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 23:00:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
Data entry locked.	System	03 Sep 2020 10:44:09
User entered 'Day 8'	System	03 Sep 2020 10:44:09

**US3672377**

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

**Form: Headache\_Day(8)**

**Generated On: 11 Aug 2021 23:00:38**

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-05T08:21:14', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'b1454c65-4579-49b8-af2c-34f689818383'	System	05 Sep 2020 12:21:20
User entered 'No interference with activity (1)'	System	05 Sep 2020 12:21:20



**US3672377**

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

**Form: Headache\_Day(8)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-05T08:21:19', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'b1454c65-4579-49b8-af2c-34f689818383'	System	05 Sep 2020 12:21:20
User entered '05 Sep 2020 08:21'	System	05 Sep 2020 12:21:20

US3672377

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 11 Aug 2021 23:00:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 10:44:09

**US3672377**

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

**Form: Headache\_Day(8)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 10:44:09

**US3672377**

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

**Form: Headache\_Day(9)**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
Data entry locked.	System	04 Sep 2020 04:37:45
User entered 'Day 9'	System	04 Sep 2020 04:37:45

**US3672377**

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

**Form: Headache\_Day(9)**

**Generated On: 11 Aug 2021 23:00:38**

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-06T00:00:13', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '66031273-7214-4773-a643-dcdabc116830'	System	06 Sep 2020 04:00:18
User entered 'No interference with activity (1)'	System	06 Sep 2020 04:00:18

**US3672377**

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

**Form: Headache\_Day(9)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-06T00:00:16', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '66031273-7214-4773-a643-dcdabc116830'	System	06 Sep 2020 04:00:18
User entered '06 Sep 2020 00:00'	System	06 Sep 2020 04:00:18

**US3672377**

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

**Form: Headache\_Day(9)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 04:37:45

**US3672377**

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

**Form: Headache\_Day(9)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 04:37:45



US3672377

Folder: Diary Dose 1 (1)

Form: Headache\_Day(10)

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
Data entry locked.	System	05 Sep 2020 12:21:20
User entered 'Day 10'	System	05 Sep 2020 12:21:20

**US3672377**

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

**Form: Headache\_Day(10)**

**Generated On: 11 Aug 2021 23:00:38**

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-07T00:28:24', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '7ef63cbe-1197-447a-b44c-7636bee12b3f'	System	07 Sep 2020 04:28:29
User entered 'None (0)'	System	07 Sep 2020 04:28:29

**US3672377**

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

**Form: Headache\_Day(10)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-07T00:28:27', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '7ef63cbe-1197-447a-b44c-7636bee12b3f'	System	07 Sep 2020 04:28:29
User entered '07 Sep 2020 00:28'	System	07 Sep 2020 04:28:29

**US3672377**

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

**Form: Headache\_Day(10)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 12:21:20

**US3672377**

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

**Form: Headache\_Day(10)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 12:21:20

US3672377

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
Data entry locked.	System	03 Sep 2020 10:43:42
User entered 'Day 8'	System	03 Sep 2020 10:43:42

US3672377

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 23:00:38

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 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-05T08:21:21', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '66b20c6a-220f-4ee3-acab-0dbe2db2c6e2'	System	05 Sep 2020 12:21:26
User entered 'No (N)'	System	05 Sep 2020 12:21:26

**US3672377**

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

**Form: Medical Attention\_Day(8)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-05T08:21:23', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '66b20c6a-220f-4ee3-acab-0dbe2db2c6e2'	System	05 Sep 2020 12:21:26
User entered '05 Sep 2020 08:21'	System	05 Sep 2020 12:21:26



**US3672377**

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

**Form: Medical Attention\_Day(8)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 10:43:42

**US3672377**

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

**Form: Medical Attention\_Day(8)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 10:43:42

US3672377

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
Data entry locked.	System	04 Sep 2020 04:37:17
User entered 'Day 9'	System	04 Sep 2020 04:37:17

US3672377

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 23:00:38

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 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-06T00:00:18', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '4f63f3d8-2b87-4d6f-902b-ffe0f50f5ea4'	System	06 Sep 2020 04:00:23
User entered 'No (N)'	System	06 Sep 2020 04:00:23

**US3672377**

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

**Form: Medical Attention\_Day(9)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-06T00:00:20', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '4f63f3d8-2b87-4d6f-902b-ffe0f50f5ea4'	System	06 Sep 2020 04:00:23
User entered '06 Sep 2020 00:00'	System	06 Sep 2020 04:00:23

US3672377

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 11 Aug 2021 23:00:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 04:37:17

**US3672377**

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

**Form: Medical Attention\_Day(9)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 04:37:17

US3672377

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 11 Aug 2021 23:00:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
Data entry locked.	System	05 Sep 2020 12:21:10
User entered 'Day 10'	System	05 Sep 2020 12:21:10



US3672377

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 11 Aug 2021 23:00:38

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 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-07T00:28:30', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '9bd1f395-2ed9-4a53-a489-1b3e9cb74844'	System	07 Sep 2020 04:28:34
User entered 'No (N)'	System	07 Sep 2020 04:28:34

**US3672377**

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

**Form: Medical Attention\_Day(10)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-09-07T00:28:32', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '9bd1f395-2ed9-4a53-a489-1b3e9cb74844'	System	07 Sep 2020 04:28:34
User entered '07 Sep 2020 00:28'	System	07 Sep 2020 04:28:34

US3672377

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 11 Aug 2021 23:00:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 12:21:10

**US3672377**

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

**Form: Medical Attention\_Day(10)**

**Generated On: 11 Aug 2021 23:00:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 12:21:10

**US3672377**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:10:06
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 17:35:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 15:07:18

US3672377

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:10:06
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 17:35:51
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	15 Sep 2020 17:05:09
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'pd added' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 15:07:25
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	14 Sep 2020 15:07:18
User entered '08 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 15:07:18

**US3672377**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:10:06
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 17:35:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Sep 2020 15:07:18

**US3672377**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:10:06
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 17:35:51
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 15:07:18



US3672377

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:10:06
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 17:35:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 15:07:31

**US3672377**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 22:10:06
User entered 'I'	System	14 Sep 2020 15:07:31

**US3672377**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:24
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 17:36:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 15:07:41

**US3672377**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:38**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:24
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 17:36:00
User entered '14 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 15:07:41

**US3672377**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:24
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 17:36:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Sep 2020 15:07:41

**US3672377**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:24
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 17:36:00
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 15:07:41

**US3672377**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:24
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 17:36:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 15:07:52

**US3672377**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:14:24
User entered '1'	System	14 Sep 2020 15:07:52



**US3672377**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:47:24
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:10:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 18:46:35

**US3672377**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:38**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:47:24
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:10:33
User entered '20 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 18:46:35

**US3672377**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:47:24
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:10:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Sep 2020 18:46:35

US3672377

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:38

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:47:24
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:10:33
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 18:46:35

**US3672377**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:47:24
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:10:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 18:46:40

**US3672377**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:47:24
User entered 'I'	System	23 Sep 2020 18:46:40

**US3672377**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:38**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:52:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 18:27:43

**US3672377**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:52:14
User entered '30 Sep 2020'	(b) (4), (b) (6)	01 Oct 2020 18:27:43



US3672377

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:00:38

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:52:14
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	01 Oct 2020 18:27:43

**US3672377**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:38**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User entered 'VISIT2'	System	01 Oct 2020 18:27:43

US3672377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	01 Oct 2020 18:27:51

US3672377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	05 Nov 2020 21:07:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 18:27:51

US3672377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:38

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 21:07:23
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 18:28:43
User entered '30 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 18:28:43
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 18:27:51
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:27:51

US3672377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	05 Nov 2020 21:07:23
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 18:28:43
Query 'Data is required. Please provide.' answered by System data change (Site from System).		01 Oct 2020 18:28:43
User entered '16:59' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 18:28:43
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 18:27:51
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:27:51

US3672377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User entered '30 Sep 2020 16:59'	System	01 Oct 2020 18:28:43
User entered empty.	System	01 Oct 2020 18:27:51

US3672377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	05 Nov 2020 21:07:23
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 18:28:43
Query 'Data is required. Please provide.' answered by System data change (Site from System).		01 Oct 2020 18:28:43
User entered '99.2' F reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 18:28:43
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 18:27:51
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:27:51



US3672377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 21:07:23
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 18:28:43
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:27:51

**US3672377**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 23:00:38**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 21:07:23
		01 Oct 2020 18:27:51

US3672377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 21:07:23
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 18:28:43
Query 'Data is required. Please provide.' answered by System data change (Site from System).		01 Oct 2020 18:28:43
User entered '106' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 18:28:43
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 18:27:51
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:27:51

**US3672377**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 23:00:38**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User entered 'bpm'	System	01 Oct 2020 18:28:43
User entered empty.	System	01 Oct 2020 18:27:51

US3672377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	05 Nov 2020 21:07:23
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 18:28:43
Query 'Data is required. Please provide.' answered by System data change (Site from System).		01 Oct 2020 18:28:43
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 18:28:43
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 18:27:51
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:27:51

US3672377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User entered 'breaths/min'	System	01 Oct 2020 18:28:43
User entered empty.	System	01 Oct 2020 18:27:51

US3672377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	05 Nov 2020 21:07:23
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 18:28:43
Query 'Data is required. Please provide.' answered by System data change (Site from System).		01 Oct 2020 18:28:43
User entered '115' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 18:28:43
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 18:27:51
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:27:51

US3672377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User entered 'mmHg'	System	01 Oct 2020 18:28:43
User entered empty.	System	01 Oct 2020 18:27:51



US3672377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	05 Nov 2020 21:07:23
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 18:28:43
Query 'Data is required. Please provide.' answered by System data change (Site from System).		01 Oct 2020 18:28:43
User entered '88' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 18:28:43
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 18:27:51
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:27:51

US3672377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 23:00:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User entered 'mmHg'	System	01 Oct 2020 18:28:43
User entered empty.	System	01 Oct 2020 18:27:51

US3672377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	01 Oct 2020 18:27:51

US3672377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 21:07:23
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	01 Oct 2020 18:29:20
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	01 Oct 2020 18:29:08
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 18:29:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 18:27:51

US3672377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:38

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:07:23
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 18:29:20
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 18:29:08
User entered '30 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 18:29:08
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 18:27:51
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:27:51

US3672377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 21:07:23
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 18:29:08
Query 'Data is required. Please provide.' answered by System data change (Site from System).		01 Oct 2020 18:29:08
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 18:27:51
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:27:51

US3672377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User entered empty.	System	01 Oct 2020 18:27:51

US3672377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 21:07:23
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 18:29:08
Query 'Data is required. Please provide.' answered by System data change (Site from System).		01 Oct 2020 18:29:08
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 18:27:51
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:27:51



**US3672377**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 23:00:38**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:07:23
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:27:51

**US3672377**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 23:00:38**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 21:07:23
		01 Oct 2020 18:27:51

US3672377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 21:07:23
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 18:29:08
Query 'Data is required. Please provide.' answered by System data change (Site from System).		01 Oct 2020 18:29:08
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 18:27:51
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:27:51

**US3672377**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 23:00:38**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User entered empty.	System	01 Oct 2020 18:27:51

US3672377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 21:07:23
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 18:29:08
Query 'Data is required. Please provide.' answered by System data change (Site from System).		01 Oct 2020 18:29:08
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 18:27:51
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:27:51

US3672377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User entered empty.	System	01 Oct 2020 18:27:51

US3672377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 21:07:23
User closed query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 18:29:08
Query 'Data is required. Please provide.' answered by System data change (Site from System).		01 Oct 2020 18:29:08
User opened query 'Data is required. Please provide.' (Site from System).	System	01 Oct 2020 18:27:51
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:27:51

US3672377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User entered empty.	System	01 Oct 2020 18:27:51



US3672377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 21:07:23
User closed query 'Data is required. Please provide.'	System	01 Oct 2020 18:29:08
(Site from System).		
Query 'Data is required. Please provide.' answered by System		01 Oct 2020 18:29:08
data change (Site from System).		
User opened query 'Data is required. Please provide.'	System	01 Oct 2020 18:27:51
(Site from System).		
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:27:51

US3672377

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 23:00:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User entered empty.	System	01 Oct 2020 18:27:51

US3672377

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:00:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 21:07:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 18:29:41

US3672377

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:00:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:07:26
User entered '30 Sep 2020'	(b) (4), (b) (6)	01 Oct 2020 18:29:41

US3672377

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:00:38

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:07:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 18:29:58

US3672377

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 23:00:38

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:07:34
User entered '30 Sep 2020'	(b) (4), (b) (6)	01 Oct 2020 18:29:58

**US3672377**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:00:38**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:07:34
User entered 'Urine (URINE)'	(b) (4), (b) (6)	01 Oct 2020 18:29:58

**US3672377**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:00:38**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:07:34
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	01 Oct 2020 18:29:58



**US3672377**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:00:38**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:07:34
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 18:29:58

**US3672377**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:00:38**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:07:34
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:29:58

**US3672377**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:00:38**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:07:34
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:29:58

**US3672377**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User entered empty.	System	01 Oct 2020 18:29:58

**US3672377**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:00:38**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:07:46
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 18:31:33

US3672377

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:00:38

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:07:46
User closed query 'Per CDM re-query: Response noted. However, no data recorded on 'Dosing Discontinuation' page. Please update else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 05:46:20
Query 'Per CDM re-query: Response noted. However, no data recorded on 'Dosing Discontinuation' page. Please update else clarify. Thank you.' answered with 'updated dosing discontinuation page. please advise. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:12:10
User opened query 'Per CDM re-query: Response noted. However, no data recorded on 'Dosing Discontinuation' page. Please update else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 10:21:32
User closed query 'Per CDM: Please complete the 'Dosing Discontinuation' page Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 10:21:32
Query 'Per CDM: Please complete the 'Dosing Discontinuation' page Thank you.' answered with 'reconciled ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 15:24:16
User opened query 'Per CDM: Please complete the 'Dosing Discontinuation' page Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 05:45:42
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	(b) (4), (b) (6)	01 Oct 2020 18:31:33

US3672377

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 21:07:46
User entered 'physician decision withdrawal of experiences an ae or saw that, in the judgement of the investigator, requires study IP withdrawal due to it's nature' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 15:24:09
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:31:33

**US3672377**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:00:38**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User entered empty.	System	01 Oct 2020 18:31:33



US3672377

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:00:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:07:46
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:31:33

US3672377

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 21:07:46
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:31:33

**US3672377**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User entered empty.	System	01 Oct 2020 18:31:33

US3672377

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:07:46
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:31:33

US3672377

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:07:46
User entered empty.	System	01 Oct 2020 18:31:33

US3672377

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 23:00:38

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User entered empty.	System	01 Oct 2020 18:31:33

US3672377

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:00:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	05 Nov 2020 21:07:51
User closed query 'Per GCL Lab Recon: GCL received an unscheduled sample for Immunogenicity Assessment dated 30 SEP 2020. However, this date matches visit 2 day 29 in EDC. Please confirm the unscheduled sample belongs to the scheduled visit with the matching date in EDC.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 16:37:58
Query 'Per GCL Lab Recon: GCL received an unscheduled sample for Immunogenicity Assessment dated 30 SEP 2020. However, this date matches visit 2 day 29 in EDC. Please confirm the unscheduled sample belongs to the scheduled visit with the matching date in EDC.' answered with 'Confirmed that Sample taken for Visit 2 Day 29 visit and not an unscheduled visit. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 15:21:14
User opened query 'Per GCL Lab Recon: GCL received an unscheduled sample for Immunogenicity Assessment dated 30 SEP 2020. However, this date matches visit 2 day 29 in EDC. Please confirm the unscheduled sample belongs to the scheduled visit with the matching date in EDC.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:09:36
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 18:32:01

US3672377

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:00:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:07:51
User entered '30 Sep 2020'	(b) (4), (b) (6)	01 Oct 2020 18:32:01



**US3672377**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:07:51
User entered '17:55'	(b) (4), (b) (6)	01 Oct 2020 18:32:01

**US3672377**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User entered '30 Sep 2020 17:55'	System	01 Oct 2020 18:32:01

US3672377

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 23:00:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 30-Sep-2020 is recorded under Visit 2 Day 29 in EDC; however, the same is reported under "Unscheduled" visit in PPD Central lab. Please reconcile the correct visit and update if applicable, else clarify.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 12:14:26
	(b) (4), (b) (6)	05 Nov 2020 21:08:41
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 30-Sep-2020 is recorded under Visit 2 Day 29 in EDC; however, the same is reported under "Unscheduled" visit in PPD Central lab. Please reconcile the correct visit and update if applicable, else clarify.' answered with 'Unscheduled kit was used for Visit 2 Day 29, swab was collected on same day of visit on 30-SEP-2020. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 15:19:26
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 30-Sep-2020 is recorded under Visit 2 Day 29 in EDC; however, the same is reported under "Unscheduled" visit in PPD Central lab. Please reconcile the correct visit and update if applicable, else clarify.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 12:12:14
User entered '30 Sep 2020'	(b) (4), (b) (6)	01 Oct 2020 18:32:21

**US3672377**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 23:00:38**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	01 Oct 2020 18:32:21

**US3672377**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 23:00:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 21:08:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 18:32:21

US3672377

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 23:00:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
User closed query 'Per source, Swab collection time was 17:10. Please verify and update accordingly' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 13:21:03
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 13:21:01
Query 'Per source, Swab collection time was 17:10. Please verify and update accordingly' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 13:48:52
DataPoint Un-verified.	(b) (4), (b) (6)	06 Nov 2020 13:48:47
User entered '17:10' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Nov 2020 13:48:47
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:08:41
User opened query 'Per source, Swab collection time was 17:10. Please verify and update accordingly' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 21:08:37
User entered '17:55'	(b) (4), (b) (6)	01 Oct 2020 18:32:21

**US3672377**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User entered '30 Sep 2020 17:10'	System	06 Nov 2020 13:48:47
User entered '30 Sep 2020 17:55'	System	01 Oct 2020 18:32:21

**US3672377**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 23:00:38**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	01 Oct 2020 18:32:21



**US3672377**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 23:00:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 21:08:41
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 18:32:21

**US3672377**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 21:08:41
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:32:21

US3672377

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User entered empty.	System	01 Oct 2020 18:32:21

US3672377

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 21:08:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 18:34:03

**US3672377**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:36:49
User entered '1'	System	01 Oct 2020 18:34:03

**US3672377**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:12:13
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 21:08:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Oct 2020 21:10:42

**US3672377**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:38**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:12:13
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	05 Nov 2020 21:08:50
User entered '11 Oct 2020'	(b) (4), (b) (6)	11 Oct 2020 21:10:42

US3672377

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:12:13
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:08:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Oct 2020 21:10:42



US3672377

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:38

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:12:13
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 21:08:50
User entered empty.	(b) (4), (b) (6)	11 Oct 2020 21:10:42

US3672377

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:12:13
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 21:08:53
		11 Oct 2020 21:13:18

**US3672377**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:12:13
User entered 'I'	System	11 Oct 2020 21:13:18

US3672377

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:17
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:53:23
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	27 Oct 2020 15:10:41
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Oct 2020 15:10:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 15:10:31
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	27 Oct 2020 15:10:31
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 15:10:31
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 23:23:48
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 23:23:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 23:23:16

**US3672377**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:38**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:17
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:53:23
User entered '14 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 15:10:31
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 23:23:48
User entered '12 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 23:23:16

US3672377

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:17
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:53:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	27 Oct 2020 15:10:41
reason for change: Data Entry Error		
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 23:23:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Oct 2020 23:23:16

US3672377

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:38

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:17
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:53:23
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 23:23:16

US3672377

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:17
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:53:33
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Oct 2020 20:12:05
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Oct 2020 20:12:05
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 20:12:05
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 23:23:31
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 23:23:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 23:23:20



**US3672377**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:11:17
User entered '1'	System	14 Oct 2020 20:12:05
User entered empty.	System	12 Oct 2020 23:23:31
User entered '1'	System	12 Oct 2020 23:23:20

US3672377

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:24
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:37:24
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:59:22
Query 'Please update to "NO" as no contact was made and no source to show that contact was attempted. ' canceled (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 17:59:20
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Apr 2021 17:45:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Apr 2021 17:45:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 17:45:03
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Apr 2021 15:29:50
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	20 Apr 2021 15:29:50
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 15:29:50
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	20 Apr 2021 15:29:02
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 15:29:02
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 15:29:02
User opened query 'Please update to "NO" as no contact was made and no source to show that contact was attempted. ' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 14:09:23
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 19:49:03
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:48:20
User closed query 'please provide source' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 17:01:12

US3672377

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Query 'please provide source' answered with ' Will follow up' (Site from CRA).	Patty Howenstine (b) (4)	29 Mar 2021 17:18:09
User opened query 'please provide source' (Site from CRA).	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 19:36:48
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	03 Dec 2020 22:08:07
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	03 Dec 2020 22:06:46
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	03 Dec 2020 22:06:46
DataPoint Un-verified.	(b) (4), (b) (6)	03 Dec 2020 22:06:46
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Dec 2020 22:06:46
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 14:04:46
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	30 Nov 2020 20:34:51
User entered 'No (N)'	(b) (4), (b) (6)	30 Nov 2020 20:34:51

US3672377

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:24
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:37:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 17:59:22
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 15:29:50
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 15:29:50
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 15:29:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:09:24
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	03 Dec 2020 22:08:07
User entered '21 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Dec 2020 22:08:07
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 14:04:46
User entered empty.	(b) (4), (b) (6)	30 Nov 2020 20:34:51

US3672377

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:24
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:37:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 17:59:22
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 15:29:50
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 15:29:50
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 15:29:50
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 14:04:46
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	30 Nov 2020 20:34:51

US3672377

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:38

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:24
User signature succeeded.	Cynthia Strout (b) (4)	22 Apr 2021 18:37:24
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:59:22
User entered 'patient was following up on worsening dermatographism' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 17:45:03
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 15:29:50
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 15:29:50
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 15:29:50
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 14:04:46
User entered 'patient was following up on worsening dermatographism'	(b) (4), (b) (6)	30 Nov 2020 20:34:51

US3672377

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:24
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
	(b) (4)	
Query 'Please update the safety call 50 folder to reflect that the Day 50 phone call was not completed. Thanks' canceled (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 13:23:03
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:56:27
User opened query 'Please update the safety call 50 folder to reflect that the Day 50 phone call was not completed. Thanks' (Site from CRA).	(b) (4), (b) (6)	30 Nov 2020 18:56:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 21:04:52

US3672377

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:05:24
User entered 'I'	System	29 Oct 2020 21:04:52



**US3672377**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:38**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:18:08
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:55:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 21:06:21

**US3672377**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:18:08
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:55:00
User entered '28 Oct 2020'	(b) (4), (b) (6)	29 Oct 2020 21:06:21

**US3672377**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:38**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:18:08
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:55:00
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	29 Oct 2020 21:06:21

**US3672377**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:38**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:18:08
User entered 'VISIT3'	System	29 Oct 2020 21:06:21

**US3672377**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:38**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:18:08
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:55:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 21:07:08

US3672377

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:18:08
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:55:14
User entered '28 Oct 2020'	(b) (4), (b) (6)	29 Oct 2020 21:07:08

US3672377

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:18:08
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:55:14
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Oct 2020 21:07:13
User entered '17:16' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 21:07:13
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Oct 2020 21:07:08
User entered '17:' (non-conformant).	(b) (4), (b) (6)	29 Oct 2020 21:07:08

**US3672377**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:18:08
User entered '28 Oct 2020 17:16'	System	29 Oct 2020 21:07:13
User entered '28 Oct 2020 17:' (non-conformant).	System	29 Oct 2020 21:07:08



**US3672377**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:18:08
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:55:14
User entered '99.0' F	(b) (4), (b) (6)	29 Oct 2020 21:07:08

**US3672377**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:38**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:18:08
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:55:14
User entered 'Oral (Oral)'	(b) (4), (b) (6)	29 Oct 2020 21:07:08

**US3672377**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:38**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:18:08
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:55:14
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:07:08

**US3672377**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:38**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:18:08
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:55:14
User entered '103'	(b) (4), (b) (6)	29 Oct 2020 21:07:08

**US3672377**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:38**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:18:08
User entered 'bpm'	System	29 Oct 2020 21:07:08

**US3672377**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:18:08
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:55:14
User entered '15'	(b) (4), (b) (6)	29 Oct 2020 21:07:08

**US3672377**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:38**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:18:08
User entered 'breaths/min'	System	29 Oct 2020 21:07:08

**US3672377**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:18:08
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:55:14
User entered '136'	(b) (4), (b) (6)	29 Oct 2020 21:07:08



US3672377

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:18:08
User entered 'mmHg'	System	29 Oct 2020 21:07:08

**US3672377**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:18:08
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:55:14
User entered '70'	(b) (4), (b) (6)	29 Oct 2020 21:07:08

US3672377

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:18:08
User entered 'mmHg'	System	29 Oct 2020 21:07:08

US3672377

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:38

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:18:08

US3672377

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:38

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:18:08

**US3672377**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 23:00:38**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:18:08
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:55:17
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 21:07:29

US3672377

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:00:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:18:08
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:55:17
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:07:29

**US3672377**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:00:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:18:08
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:55:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 21:07:49



US3672377

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:00:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:18:08
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:55:28
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28Oct2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile and confirm the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28Oct2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile and confirm the correct Visit and update if applicable. Else clarify, thank you.' answered with 'Date is correct.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 19:18:15
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28Oct2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile and confirm the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM). User entered '28 Oct 2020'	(b) (4), (b) (6)	16 Nov 2020 15:02:56
	(b) (4), (b) (6)	08 Nov 2020 15:31:44
	(b) (4), (b) (6)	29 Oct 2020 21:07:49

**US3672377**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:18:08
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:55:28
User entered '17:40'	(b) (4), (b) (6)	29 Oct 2020 21:07:49

**US3672377**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:18:08
User entered '28 Oct 2020 17:40'	System	29 Oct 2020 21:07:49

US3672377

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:18:08
User signature succeeded.	Cynthia Strout (b) (4)	17 Feb 2021 21:07:07
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:55:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 21:07:53

**US3672377**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:18:08
User entered 'I'	System	29 Oct 2020 21:07:53

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:52:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:54
Data entry locked.	System	28 Aug 2020 17:51:22
User entered 'Day 64'	System	28 Aug 2020 17:51:22

US3672377

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[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 13:52:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:54

US3672377

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

Have you been exposed to someone with 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 13:52:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:54



**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Please 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 13:52:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:54

US3672377

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

[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 13:52:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:54

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:52:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:54

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:52:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:54

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:52:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:54

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:52:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:54

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:52:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:54

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:52:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:54



**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:52:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:54

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:52:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:54

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:52:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:54

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:52:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:54

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:52:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:54

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:52:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:54

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:52:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:54

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:52:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:54



**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:52:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:54

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:52:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:54

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:52:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:54

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Please 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 13:52:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:54

US3672377

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

[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 13:52:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:54

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Please 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 13:52:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:54

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:52:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:54

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:52:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:54
Data entry locked.	System	28 Aug 2020 17:51:22
User entered '28 Oct 2020 00:01'	System	28 Aug 2020 17:51:22



**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:52:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 19:56:54
Data entry locked.	System	28 Aug 2020 17:51:22
User entered '01 Nov 2020 23:59'	System	28 Aug 2020 17:51:22

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
Data entry locked.	System	28 Aug 2020 17:51:22
User entered 'Day 71'	System	28 Aug 2020 17:51:22

US3672377

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-11-04T23:40:42', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '0049f859-ee50-452f-a987-ef7346cfd8f8'	System	05 Nov 2020 04:43:46
User entered 'No (N)'	System	05 Nov 2020 04:43:46

US3672377

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-11-04T23:43:36', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '0049f859-ee50-452f-a987-ef7346cfd8f8'	System	05 Nov 2020 04:43:46
User entered 'No (N)'	System	05 Nov 2020 04:43:46

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-11-04T23:43:40', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '0049f859-ee50-452f-a987-ef7346cfd8f8'	System	05 Nov 2020 04:43:46
User entered '04 Nov 2020 23:43:40'	System	05 Nov 2020 04:43:46

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
Data entry locked.	System	28 Aug 2020 17:51:22
User entered '04 Nov 2020 00:01'	System	28 Aug 2020 17:51:22

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
Data entry locked.	System	28 Aug 2020 17:51:22
User entered '08 Nov 2020 23:59'	System	28 Aug 2020 17:51:22

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
Data entry locked.	System	28 Aug 2020 17:51:22
User entered 'Day 78'	System	28 Aug 2020 17:51:22



US3672377

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-11-11T17:57:56', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'b4daee90-f88d-4ee8-be6d-35f03d6687a0'	System	11 Nov 2020 22:58:33
User entered 'No (N)'	System	11 Nov 2020 22:58:33

US3672377

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 23:00:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-11-11T17:58:05', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'b4daee90-f88d-4ee8-be6d-35f03d6687a0'	System	11 Nov 2020 22:58:33
User entered 'Yes (Y)'	System	11 Nov 2020 22:58:33

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Please 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)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-11-11T17:58:15', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'b4daee90-f88d-4ee8-be6d-35f03d6687a0'	System	11 Nov 2020 22:58:33
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Nov 2020 22:58:33

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-11-11T17:58:19', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'b4daee90-f88d-4ee8-be6d-35f03d6687a0'	System	11 Nov 2020 22:58:33
User entered '11 Nov 2020 17:58:19'	System	11 Nov 2020 22:58:33

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
Data entry locked.	System	28 Aug 2020 17:51:22
User entered '11 Nov 2020 00:01'	System	28 Aug 2020 17:51:22

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 07:47:54
Data entry locked.	System	28 Aug 2020 17:51:22
User entered '15 Nov 2020 23:59'	System	28 Aug 2020 17:51:22

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 19:56:54

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[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 (c847ca7f888da112)', Time: '2020-11-23T00:08:12', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '5a539621-11d7-4280-8a8e-e96eefcb8b9d'	System	23 Nov 2020 05:08:20
User entered 'No (N)'	System	23 Nov 2020 05:08:20



**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Have you been exposed to someone with 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 (c847ca7f888da112)', Time: '2020-11-23T00:08:14', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '5a539621-11d7-4280-8a8e-e96eefcb8b9d'	System	23 Nov 2020 05:08:20
User entered 'No (N)'	System	23 Nov 2020 05:08:20

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-11-23T00:08:16', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '5a539621-11d7-4280-8a8e-e96eefcb8b9d'	System	23 Nov 2020 05:08:20
User entered '23 Nov 2020 00:08:16'	System	23 Nov 2020 05:08:20

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 19:56:54

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[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 (c847ca7f888da112)', Time: '2020-12-02T21:26:24', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '3d26d605-8bb2-42f4-83c8-17ed473d6f52'	System	03 Dec 2020 02:26:34
User entered 'No (N)'	System	03 Dec 2020 02:26:34

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

Have you been exposed to someone with 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 (c847ca7f888da112)', Time: '2020-12-02T21:26:29', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '3d26d605-8bb2-42f4-83c8-17ed473d6f52'	System	03 Dec 2020 02:26:34
User entered 'No (N)'	System	03 Dec 2020 02:26:34

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-12-02T21:26:31', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '3d26d605-8bb2-42f4-83c8-17ed473d6f52'	System	03 Dec 2020 02:26:34
User entered '02 Dec 2020 21:26:31'	System	03 Dec 2020 02:26:34



**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[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 (c847ca7f888da112)', Time: '2020-12-14T20:41:19', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'c21c457f-8ee2-4713-8d46-bb1614a604fe'	System	15 Dec 2020 01:41:35
User entered 'No (N)'	System	15 Dec 2020 01:41:35

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

Have you been exposed to someone with 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 (c847ca7f888da112)', Time: '2020-12-14T20:41:29', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'c21c457f-8ee2-4713-8d46-bb1614a604fe'	System	15 Dec 2020 01:41:35
User entered 'No (N)'	System	15 Dec 2020 01:41:35



**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-12-14T20:41:31', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'c21c457f-8ee2-4713-8d46-bb1614a604fe' User entered '14 Dec 2020 20:41:31'	System	15 Dec 2020 01:41:35
	System	15 Dec 2020 01:41:35

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[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 (c847ca7f888da112)', Time: '2020-12-23T18:41:24', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '8f987d2a-f7be-479f-bc46-8de3f200f790'	System	23 Dec 2020 23:41:35
User entered 'No (N)'	System	23 Dec 2020 23:41:35

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

Have you been exposed to someone with 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 (c847ca7f888da112)', Time: '2020-12-23T18:41:29', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '8f987d2a-f7be-479f-bc46-8de3f200f790'	System	23 Dec 2020 23:41:35
User entered 'No (N)'	System	23 Dec 2020 23:41:35

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-12-23T18:41:31', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '8f987d2a-f7be-479f-bc46-8de3f200f790'	System	23 Dec 2020 23:41:35
User entered '23 Dec 2020 18:41:31'	System	23 Dec 2020 23:41:35

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 19:56:54



**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[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 (c847ca7f888da112)', Time: '2020-12-31T18:04:48', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '80a8b385-d9de-471a-8c28-8fc8e0e064e7'	System	31 Dec 2020 23:05:05
User entered 'No (N)'	System	31 Dec 2020 23:05:05

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

Have you been exposed to someone with 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 (c847ca7f888da112)', Time: '2020-12-31T18:04:55', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '80a8b385-d9de-471a-8c28-8fc8e0e064e7'	System	31 Dec 2020 23:05:05
User entered 'No (N)'	System	31 Dec 2020 23:05:05

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2020-12-31T18:05:01', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '80a8b385-d9de-471a-8c28-8fc8e0e064e7' User entered '31 Dec 2020 18:05:01'	System	31 Dec 2020 23:05:05
	System	31 Dec 2020 23:05:05

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 19:56:54



**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[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 (c847ca7f888da112)', Time: '2021-01-07T12:44:48', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '4e0b198e-573b-48fb-91a8-a0fd32fdc4a7'	System	07 Jan 2021 17:44:57
User entered 'No (N)'	System	07 Jan 2021 17:44:57

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

Have you been exposed to someone with 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 (c847ca7f888da112)', Time: '2021-01-07T12:44:51', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '4e0b198e-573b-48fb-91a8-a0fd32fdc4a7'	System	07 Jan 2021 17:44:57
User entered 'No (N)'	System	07 Jan 2021 17:44:57

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2021-01-07T12:44:53', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '4e0b198e-573b-48fb-91a8-a0fd32fdc4a7' User entered '07 Jan 2021 12:44:53'	System	07 Jan 2021 17:44:57

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[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 (c847ca7f888da112)', Time: '2021-01-13T18:11:26', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'd8a0063b-229b-451b-ae74-ba8d232bf042'	System	13 Jan 2021 23:11:36
User entered 'No (N)'	System	13 Jan 2021 23:11:36

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Have you been exposed to someone with 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 (c847ca7f888da112)', Time: '2021-01-13T18:11:27', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'd8a0063b-229b-451b-ae74-ba8d232bf042'	System	13 Jan 2021 23:11:36
User entered 'No (N)'	System	13 Jan 2021 23:11:36



**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2021-01-13T18:11:32', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'd8a0063b-229b-451b-ae74-ba8d232bf042'	System	13 Jan 2021 23:11:36
User entered '13 Jan 2021 18:11:32'	System	13 Jan 2021 23:11:36

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[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 (c847ca7f888da112)', Time: '2021-01-21T18:02:00', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'fc53acc1-2e4c-401e-9156-eda18813b57b'	System	21 Jan 2021 23:02:48
User entered 'No (N)'	System	21 Jan 2021 23:02:48

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

Have you been exposed to someone with 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 (c847ca7f888da112)', Time: '2021-01-21T18:02:01', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'fc53acc1-2e4c-401e-9156-eda18813b57b'	System	21 Jan 2021 23:02:48
User entered 'No (N)'	System	21 Jan 2021 23:02:48

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2021-01-21T18:02:03', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'fc53acc1-2e4c-401e-9156-eda18813b57b' User entered '21 Jan 2021 18:02:03'	System	21 Jan 2021 23:02:48
	System	21 Jan 2021 23:02:48

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 19:56:54



**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[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 (c847ca7f888da112)', Time: '2021-01-26T12:45:04', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'f90118d2-2159-4d1b-b3b1-b550121ba302'	System	26 Jan 2021 18:42:11
User entered 'No (N)'	System	26 Jan 2021 18:42:11

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

Have you been exposed to someone with 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 (c847ca7f888da112)', Time: '2021-01-26T12:45:06', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'f90118d2-2159-4d1b-b3b1-b550121ba302'	System	26 Jan 2021 18:42:11
User entered 'No (N)'	System	26 Jan 2021 18:42:11

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2021-01-26T12:45:08', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'f90118d2-2159-4d1b-b3b1-b550121ba302' User entered '26 Jan 2021 12:45:08'	System	26 Jan 2021 18:42:11

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 19:56:54



**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[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 (c847ca7f888da112)', Time: '2021-02-02T12:05:19', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'c85949e7-3e55-4b3d-b051-7b8ffe6c77d1'	System	02 Feb 2021 17:10:37
User entered 'No (N)'	System	02 Feb 2021 17:10:37

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

Have you been exposed to someone with 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 (c847ca7f888da112)', Time: '2021-02-02T12:05:21', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'c85949e7-3e55-4b3d-b051-7b8ffe6c77d1'	System	02 Feb 2021 17:10:37
User entered 'No (N)'	System	02 Feb 2021 17:10:37

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2021-02-02T12:05:23', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'c85949e7-3e55-4b3d-b051-7b8ffe6c77d1'	System	02 Feb 2021 17:10:37
User entered '02 Feb 2021 12:05:23'	System	02 Feb 2021 17:10:37

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[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 (c847ca7f888da112)', Time: '2021-02-10T17:19:13', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '4e70acf3-6217-4785-a09e-f20537ca907e'	System	10 Feb 2021 22:19:22
User entered 'No (N)'	System	10 Feb 2021 22:19:22

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

Have you been exposed to someone with 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 (c847ca7f888da112)', Time: '2021-02-10T17:19:14', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '4e70acf3-6217-4785-a09e-f20537ca907e'	System	10 Feb 2021 22:19:22
User entered 'No (N)'	System	10 Feb 2021 22:19:22



**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2021-02-10T17:19:16', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '4e70acf3-6217-4785-a09e-f20537ca907e'	System	10 Feb 2021 22:19:22
User entered '10 Feb 2021 17:19:16'	System	10 Feb 2021 22:19:22

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[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 (c847ca7f888da112)', Time: '2021-02-17T18:12:52', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '8eb4c03e-4c20-4384-bb20-f071e9ecfec5'	System	17 Feb 2021 23:15:48
User entered 'No (N)'	System	17 Feb 2021 23:15:48

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

Have you been exposed to someone with 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 (c847ca7f888da112)', Time: '2021-02-17T18:12:53', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '8eb4c03e-4c20-4384-bb20-f071e9ecfec5'	System	17 Feb 2021 23:15:48
User entered 'No (N)'	System	17 Feb 2021 23:15:48

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2021-02-17T18:12:59', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '8eb4c03e-4c20-4384-bb20-f071e9ecfec5'	System	17 Feb 2021 23:15:48
User entered '17 Feb 2021 18:12:59'	System	17 Feb 2021 23:15:48

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 19:56:54



**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[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 (c847ca7f888da112)', Time: '2021-02-23T12:03:43', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '4a8ae6f4-bfe9-4cc1-bd7f-618bc52f5421'	System	23 Feb 2021 17:16:07
User entered 'No (N)'	System	23 Feb 2021 17:16:07

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

Have you been exposed to someone with 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 (c847ca7f888da112)', Time: '2021-02-23T12:03:45', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '4a8ae6f4-bfe9-4cc1-bd7f-618bc52f5421'	System	23 Feb 2021 17:16:07
User entered 'No (N)'	System	23 Feb 2021 17:16:07

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c847ca7f888da112)', Time: '2021-02-23T12:03:46', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '4a8ae6f4-bfe9-4cc1-bd7f-618bc52f5421'	System	23 Feb 2021 17:16:07
User entered '23 Feb 2021 12:03:46'	System	23 Feb 2021 17:16:07

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 19:56:54



**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[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 (46e97fcc891d4d9f)', Time: '2021-03-02T12:03:22-05:00', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '9338c659-1993-4d5e-a9ce-bcd76a1be094'	System	02 Mar 2021 17:11:18
User entered 'No (N)'	System	02 Mar 2021 17:11:18

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

Have you been exposed to someone with 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 (46e97fcc891d4d9f)', Time: '2021-03-02T12:03:24-05:00', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '9338c659-1993-4d5e-a9ce-bcd76a1be094'	System	02 Mar 2021 17:11:18
User entered 'No (N)'	System	02 Mar 2021 17:11:18

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46e97fcc891d4d9f)', Time: '2021-03-02T12:03:26-05:00', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '9338c659-1993-4d5e-a9ce-bcd76a1be094'	System	02 Mar 2021 17:11:18
User entered '02 Mar 2021 12:03:26'	System	02 Mar 2021 17:11:18

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[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 (46e97fcc891d4d9f)', Time: '2021-03-09T23:31:06-05:00', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '734e932c-7a45-493f-a992-40308d77d4e6'	System	10 Mar 2021 04:31:15
User entered 'No (N)'	System	10 Mar 2021 04:31:15

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

Have you been exposed to someone with 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 (46e97fcc891d4d9f)', Time: '2021-03-09T23:31:07-05:00', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '734e932c-7a45-493f-a992-40308d77d4e6'	System	10 Mar 2021 04:31:15
User entered 'No (N)'	System	10 Mar 2021 04:31:15



**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46e97fcc891d4d9f)', Time: '2021-03-09T23:31:10-05:00', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '734e932c-7a45-493f-a992-40308d77d4e6' User entered '09 Mar 2021 23:31:10'	System	10 Mar 2021 04:31:15
	System	10 Mar 2021 04:31:15

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[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 (46e97fcc891d4d9f)', Time: '2021-03-16T13:28:45-04:00', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '9e231d4d-035d-4eaf-859f-eee578780685'	System	16 Mar 2021 17:28:54
User entered 'No (N)'	System	16 Mar 2021 17:28:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

Have you been exposed to someone with 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 (46e97fcc891d4d9f)', Time: '2021-03-16T13:28:46-04:00', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '9e231d4d-035d-4eaf-859f-eee578780685'	System	16 Mar 2021 17:28:54
User entered 'No (N)'	System	16 Mar 2021 17:28:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46e97fcc891d4d9f)', Time: '2021-03-16T13:28:48-04:00', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '9e231d4d-035d-4eaf-859f-eee578780685' User entered '16 Mar 2021 13:28:48'	System	16 Mar 2021 17:28:54
	System	16 Mar 2021 17:28:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 19:56:54



**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[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 (46e97fcc891d4d9f)', Time: '2021-03-23T12:02:16-04:00', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '8157ee4a-771f-4ed3-b1d2-e868a9a48ba4'	System	23 Mar 2021 16:06:18
User entered 'No (N)'	System	23 Mar 2021 16:06:18

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

Have you been exposed to someone with 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 (46e97fcc891d4d9f)', Time: '2021-03-23T12:02:19-04:00', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '8157ee4a-771f-4ed3-b1d2-e868a9a48ba4'	System	23 Mar 2021 16:06:18
User entered 'No (N)'	System	23 Mar 2021 16:06:18

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46e97fcc891d4d9f)', Time: '2021-03-23T12:02:21-04:00', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '8157ee4a-771f-4ed3-b1d2-e868a9a48ba4' User entered '23 Mar 2021 12:02:21'	System	23 Mar 2021 16:06:18
	System	23 Mar 2021 16:06:18

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 19:56:54



**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[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 (46e97fcc891d4d9f)', Time: '2021-03-30T12:00:45-04:00', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '9a73376e-9d7a-4ca1-bf6a-235253ff90e0' User entered 'No (N)'	System	30 Mar 2021 16:02:29
	System	30 Mar 2021 16:02:29

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

Have you been exposed to someone with 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 (46e97fcc891d4d9f)', Time: '2021-03-30T12:00:46-04:00', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '9a73376e-9d7a-4ca1-bf6a-235253ff90e0'	System	30 Mar 2021 16:02:29
User entered 'No (N)'	System	30 Mar 2021 16:02:29

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46e97fcc891d4d9f)', Time: '2021-03-30T12:00:48-04:00', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '9a73376e-9d7a-4ca1-bf6a-235253ff90e0' User entered '30 Mar 2021 12:00:48'	System	30 Mar 2021 16:02:29
	System	30 Mar 2021 16:02:29

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[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 (46e97fcc891d4d9f)', Time: '2021-04-08T13:25:00-04:00', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '015c89fe-6ea0-4148-8ab0-9f622e24a606'	System	08 Apr 2021 17:26:27
User entered 'No (N)'	System	08 Apr 2021 17:26:27

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

Have you been exposed to someone with 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 (46e97fcc891d4d9f)', Time: '2021-04-08T13:25:02-04:00', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '015c89fe-6ea0-4148-8ab0-9f622e24a606'	System	08 Apr 2021 17:26:27
User entered 'No (N)'	System	08 Apr 2021 17:26:27



**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46e97fcc891d4d9f)', Time: '2021-04-08T13:26:24-04:00', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '015c89fe-6ea0-4148-8ab0-9f622e24a606'	System	08 Apr 2021 17:26:27
User entered '08 Apr 2021 13:26:24'	System	08 Apr 2021 17:26:27

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[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 (46e97fcc891d4d9f)', Time: '2021-04-13T12:53:19-04:00', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'cdf0c69e-54a9-49d2-9567-d6f2e1c80bce' User entered 'No (N)'	System	13 Apr 2021 16:53:27
	System	13 Apr 2021 16:53:27

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

Have you been exposed to someone with 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 (46e97fcc891d4d9f)', Time: '2021-04-13T12:53:20-04:00', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'cdf0c69e-54a9-49d2-9567-d6f2e1c80bce'	System	13 Apr 2021 16:53:27
User entered 'No (N)'	System	13 Apr 2021 16:53:27

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46e97fcc891d4d9f)', Time: '2021-04-13T12:53:22-04:00', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: 'cdf0c69e-54a9-49d2-9567-d6f2e1c80bce'	System	13 Apr 2021 16:53:27
User entered '13 Apr 2021 12:53:22'	System	13 Apr 2021 16:53:27

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 19:56:54



**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[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 (46e97fcc891d4d9f)', Time: '2021-04-20T12:03:05-04:00', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '875b8624-1d63-4df6-9a6b-b1961cf15052'	System	20 Apr 2021 16:08:16
User entered 'No (N)'	System	20 Apr 2021 16:08:16

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

Have you been exposed to someone with 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 (46e97fcc891d4d9f)', Time: '2021-04-20T12:03:09-04:00', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '875b8624-1d63-4df6-9a6b-b1961cf15052'	System	20 Apr 2021 16:08:16
User entered 'No (N)'	System	20 Apr 2021 16:08:16

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46e97fcc891d4d9f)', Time: '2021-04-20T12:03:11-04:00', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '875b8624-1d63-4df6-9a6b-b1961cf15052'	System	20 Apr 2021 16:08:16
User entered '20 Apr 2021 12:03:11'	System	20 Apr 2021 16:08:16

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 19:56:54



**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[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 (46e97fcc891d4d9f)', Time: '2021-04-27T12:03:01-04:00', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '3b1bb03a-9edc-4a3a-9bf7-0d8af4e1015b'	System	29 Apr 2021 04:10:37
User entered 'No (N)'	System	29 Apr 2021 04:10:37

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

Have you been exposed to someone with 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 (46e97fcc891d4d9f)', Time: '2021-04-27T12:03:02-04:00', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '3b1bb03a-9edc-4a3a-9bf7-0d8af4e1015b'	System	29 Apr 2021 04:10:37
User entered 'No (N)'	System	29 Apr 2021 04:10:37

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46e97fcc891d4d9f)', Time: '2021-04-27T12:03:04-04:00', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '3b1bb03a-9edc-4a3a-9bf7-0d8af4e1015b' User entered '27 Apr 2021 12:03:04'	System	29 Apr 2021 04:10:37
	System	29 Apr 2021 04:10:37

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 19:56:54



**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 19:56:54



**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 19:56:54



**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 19:56:54



**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 19:56:54



**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 19:56:54



**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 19:56:54



**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 19:56:54



**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 19:56:54



**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 19:56:54



**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 19:56:54



**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 19:56:54



**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 19:56:54



**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 19:56:54



**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 19:56:54



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 19:56:54



**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 19:56:54



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 19:56:54



**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 19:56:54



**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 19:56:54



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 19:56:54



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 19:56:54

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 19:56:54

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 19:56:54



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 19:56:54

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 19:56:54

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 19:56:54

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 19:56:54



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 19:56:54

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 19:56:54



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 19:56:54

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 19:56:54

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 19:56:54

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 19:56:54



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 19:56:54

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 19:56:54



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 19:56:54

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 19:56:54

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 19:56:54

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 19:56:54



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 19:56:54



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 19:56:54

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 19:56:54

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 19:56:54



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 19:56:54

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '23 Oct 2022 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '27 Oct 2022 23:59'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 19:56:54



**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '30 Oct 2022 00:01'	System	19 Nov 2020 19:56:54

**US3672377**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 23:00:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:56:54
Amendment Manager: User entered '03 Nov 2022 23:59'	System	19 Nov 2020 19:56:54

US3672377

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 23:00:38**

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 13:52:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46e97fcc891d4d9f)', Time: '2021-03-02T12:03:36-05:00', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '14ac22e7-9536-40b8-bd6a-17130125851a'	System	02 Mar 2021 17:12:00
User entered 'No (N)'	System	02 Mar 2021 17:12:00

**US3672377**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 23:00:38**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 13:52:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (46e97fcc891d4d9f)', Time: '2021-03-02T12:03:52-05:00', User OID: 'PatientReportedOutcome (US3672377)', ODM File OID: '14ac22e7-9536-40b8-bd6a-17130125851a'	System	02 Mar 2021 17:12:00
User entered '02 Mar 2021 12:03:52'	System	02 Mar 2021 17:12:00

**US3672377**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:10
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:29:50
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 17:32:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Nov 2020 18:16:04

**US3672377**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:38**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:10
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:29:50
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 17:32:01
User entered '25 Nov 2020'	(b) (4), (b) (6)	25 Nov 2020 18:16:04

US3672377

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:10
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:29:50
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 17:32:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	25 Nov 2020 18:16:04

**US3672377**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:10
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:29:50
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 17:32:01
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 18:16:04



**US3672377**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:10
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:29:50
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 17:31:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Nov 2020 18:16:07

**US3672377**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:45:10
User entered 'I'	System	25 Nov 2020 18:16:07

**US3672377**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:23:25
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:42:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:29:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Feb 2021 21:51:56

**US3672377**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:38**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:23:25
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:42:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:29:50
User entered '5 Jan 2021'	(b) (4), (b) (6)	01 Feb 2021 21:51:56

**US3672377**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:23:25
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:42:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:29:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Feb 2021 21:51:56

**US3672377**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:23:25
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:42:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:29:50
User entered empty.	(b) (4), (b) (6)	01 Feb 2021 21:51:56

**US3672377**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:23:25
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:42:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:29:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Feb 2021 21:52:01

**US3672377**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:23:25
User entered '1'	System	01 Feb 2021 21:52:01



**US3672377**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:23:25
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:43:03
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:29:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Feb 2021 21:52:10

**US3672377**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:38**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:23:25
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:43:03
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:29:50
User entered '1 Feb 2021'	(b) (4), (b) (6)	01 Feb 2021 21:52:10

**US3672377**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:23:25
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:43:03
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:29:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Feb 2021 21:52:10

US3672377

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:38

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:23:25
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:43:03
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:29:50
User entered empty.	(b) (4), (b) (6)	01 Feb 2021 21:52:10

**US3672377**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:23:25
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:44:08
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:29:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Feb 2021 21:52:17

**US3672377**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:23:25
User entered 'I'	System	01 Feb 2021 21:52:17

**US3672377**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:23:25
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:44:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:29:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Mar 2021 14:06:00

**US3672377**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:38**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:23:25
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:44:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:29:50
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:06:00



**US3672377**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:23:25
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:44:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:29:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:06:00

US3672377

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:38

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:23:25
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:44:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:29:50
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:06:00

US3672377

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:23:25
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:44:56
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:29:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Mar 2021 14:06:07

**US3672377**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:23:25
User entered 'I'	System	01 Mar 2021 14:06:07

**US3672377**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:38**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:32:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:05:57

**US3672377**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:38**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:32:51
User entered '1 Apr 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:05:57

US3672377

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 23:00:38

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 15:32:51
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:05:57

**US3672377**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:38**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	05 Apr 2021 15:05:57



US3672377

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:32:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:06:15

**US3672377**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:38**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:32:51
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:06:15

**US3672377**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:38**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:32:51
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 15:06:15

**US3672377**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:38**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 15:06:15

US3672377

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:38

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:32:51
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 15:06:15

US3672377

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:38

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:32:51
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 15:06:15

**US3672377**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:38**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:32:51
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 15:06:15

**US3672377**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:38**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:32:51
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 15:06:15



**US3672377**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:38**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 15:06:15

US3672377

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:32:51
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 15:06:15

**US3672377**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:38**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 15:06:15

US3672377

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:32:51
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:06:15

**US3672377**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:38**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 15:06:15

US3672377

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 23:00:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:32:51
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 15:06:15

**US3672377**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 23:00:38**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Apr 2021 15:06:15

US3672377

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:00:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:32:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:06:19



US3672377

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 23:00:38

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:32:51
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 15:06:19

US3672377

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:00:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:32:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:06:36

US3672377

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:00:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:32:51
User entered '1 Apr 2021'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:06:36

**US3672377**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:00:38**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:32:51
User entered '17:15'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:06:36

**US3672377**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:00:38**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '1 Apr 2021 17:15'	System	05 Apr 2021 15:06:36

US3672377

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:32:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 15:06:24

**US3672377**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Apr 2021 15:06:24

**US3672377**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	28 Apr 2021 10:27:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:53:36



US3672377

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 23:00:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	28 Apr 2021 10:27:19
User entered '26 Apr 2021'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:53:36

**US3672377**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	28 Apr 2021 10:27:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:53:36

**US3672377**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 23:00:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	28 Apr 2021 10:27:19
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:53:36

US3672377

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 23:00:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	28 Apr 2021 10:27:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Apr 2021 15:53:43

**US3672377**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 23:00:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Apr 2021 15:53:43

**US3672377**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:38**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:32
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:45:09
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:29:50
User entered 'Yes (Y)'	(b) (4) Patty Howenstine (b) (4) (b) (4)	05 Feb 2021 14:19:53

**US3672377**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:38**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:32
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:45:09
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:29:50
User entered '4 Feb 2021'	(b) (4) Patty Howenstine (b) (4) (b) (4)	05 Feb 2021 14:19:53

**US3672377**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:38**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:32
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:45:09
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:29:50
User entered 'Clinic (Clinic)'	(b) (4) Patty Howenstine (b) (4) (b) (4)	05 Feb 2021 14:19:53



**US3672377**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 23:00:38**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:32
User entered 'UNBLND_DECIDE'	System	05 Feb 2021 14:19:53

US3672377

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 23:00:38

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:32
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:49:37
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:32:51
User closed query 'Per sponsor review, this field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:38:02
User closed query 'please obtain ICF IRB approved 6Jan21' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 16:59:35
Query 'Per sponsor review, this field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5.' answered with 'Accession number and tracking details ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 19:31:05
DataPoint Un-verified.	(b) (4), (b) (6)	08 Apr 2021 19:30:44
Signature has been broken.	(b) (4), (b) (6)	08 Apr 2021 19:30:44
User entered '04 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 19:30:44

US3672377

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 23:00:38

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per sponsor review, this field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 17:55:55
Query 'please obtain ICF IRB approved 6Jan21' answered with 'Next Visit 4/1 - will get' (Site from CRA).	Patty Howenstine (b) (4)	29 Mar 2021 17:20:19
User opened query 'please obtain ICF IRB approved 6Jan21' (Site from CRA).	(b) (4), (b) (6)	23 Mar 2021 19:46:33
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:45:57
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:29:50
User entered '23 Dec 2020'	Patty Howenstine (b) (4)	05 Feb 2021 14:20:32

**US3672377**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:00:38**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:32
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:32:51
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:20:52

US3672377

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 23:00:38

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:32
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:45:57
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:29:50
User entered 'Yes (Y)'	(b) (4) Patty Howenstine (b) (4) (b) (4)	05 Feb 2021 14:20:32

**US3672377**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:00:38**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:32
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:32:51
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:20:52

**US3672377**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:00:38**

**Date of unblinding (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:32
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:45:57
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:29:50
User entered '4 Feb 2021'	(b) (4) Patty Howenstine (b) (4) (b) (4)	05 Feb 2021 14:20:32

US3672377

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 23:00:38

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:32
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:45:57
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:29:50
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Patty Howenstine (b) (4) (b) (4)	05 Feb 2021 14:20:32



**US3672377**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:00:38**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:32
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:45:57
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:29:50
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Patty Howenstine (b) (4) (b) (4)	05 Feb 2021 14:20:32

**US3672377**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:00:38**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:32
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:45:57
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:29:50
User entered 'Not Administered (NA)'	(b) (4) Patty Howenstine (b) (4) (b) (4)	05 Feb 2021 14:20:32

US3672377

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 23:00:38

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:32
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:45:57
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:29:50
User entered 'No (N)'	(b) (4) Patty Howenstine (b) (4) (b) (4)	05 Feb 2021 14:20:32

**US3672377**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:00:38**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:32
User entered empty.	System	05 Feb 2021 14:20:32

**US3672377**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 23:00:38**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:32
User entered empty.	System	05 Feb 2021 14:20:32

**US3672377**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:00:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:32
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:47:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:29:50
User entered 'Yes (Y)'	(b) (4) Patty Howenstine (b) (4) (b) (4)	05 Feb 2021 14:22:25

US3672377

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:00:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:32
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:47:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:29:50
User entered '4 Feb 2021'	(b) (4) Patty Howenstine (b) (4) (b) (4)	05 Feb 2021 14:22:25

**US3672377**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 23:00:38**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:32
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:47:37
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:29:50
User entered '17:35'	(b) (4) Patty Howenstine (b) (4) (b) (4)	05 Feb 2021 14:22:25



US3672377

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 23:00:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:32
User entered '4 Feb 2021 17:35'	System	05 Feb 2021 14:22:25

**US3672377**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 23:00:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:32
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:47:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:29:50
User entered 'Yes (Y)'	(b) (4) Patty Howenstine (b) (4) (b) (4)	05 Feb 2021 14:22:34

**US3672377**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 23:00:38**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:32
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:47:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:29:50
User entered '4 Feb 2021'	(b) (4) Patty Howenstine (b) (4)	05 Feb 2021 14:22:34

**US3672377**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 23:00:38**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:32
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:47:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:29:50
User entered '17:30'	(b) (4) Patty Howenstine (b) (4)	05 Feb 2021 14:22:34

**US3672377**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 23:00:38**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:32
User entered '4 Feb 2021 17:30'	System	05 Feb 2021 14:22:34

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 11 Aug 2021 23:00:38**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:06:38
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:29:50
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 20:05:08

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:00:38**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:44

US3672377

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:00:38

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Dental and oral soft tissue infections, PT: Tooth infection, LLT: Tooth infection - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 20:08:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 20:08:45
Data point term sent to Coder	System	22 Sep 2020 20:07:07
User entered 'tooth infection'	(b) (4), (b) (6)	22 Sep 2020 20:06:48



**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:00:38**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 20:06:48

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:00:38**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 20:06:48

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:00:38**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 20:06:48

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:00:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '09 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 20:06:48

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:00:38**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 20:06:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:00:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:44
User entered empty.	System	22 Sep 2020 20:06:48

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:00:38**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Nov 2020 16:37:05
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 19:16:29
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 20:06:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:00:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '17 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Nov 2020 16:37:05
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 19:16:29
User entered '19 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 20:06:48



**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:00:38**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 20:06:48

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:00:38**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:44
User entered empty.	System	22 Sep 2020 20:06:48

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:00:38**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	22 Sep 2020 20:06:48

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:00:38**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 20:06:48

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:00:38**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 20:06:48

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:00:38**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 20:06:48

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:00:38**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 20:06:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:00:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 20:06:48



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:00:38

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 20:06:48

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:00:38**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 20:06:48

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:00:38**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 20:06:48

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:00:38**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 20:06:48

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:00:38**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 20:06:48

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:00:38**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 20:06:48

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:00:38**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	22 Sep 2020 20:06:48

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:00:38**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	22 Sep 2020 20:06:48



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:00:38

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 20:06:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Sep 2020 20:06:57
User entered 'None (NONE)' reason for change:	(b) (4), (b) (6)	22 Sep 2020 20:06:57
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 20:06:48
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 20:06:48

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:00:38**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 20:06:48

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:00:38**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'l'	(b) (4), (b) (6)	22 Sep 2020 20:06:48

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:00:38**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 20:06:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:00:38

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	30 Nov 2020 18:52:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Nov 2020 16:37:05
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 19:16:29
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	22 Sep 2020 20:06:48

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:00:38**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 20:06:48

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:00:38**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:44
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 20:06:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 23:00:38

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:44
User entered '0'	System	22 Sep 2020 20:06:48



**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:00:38**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:44
User entered '1'	System	22 Sep 2020 20:06:48

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 23:00:38**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:44

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:00:38**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:00:38

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 20:11:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 20:11:41
Data point term sent to Coder	System	22 Sep 2020 20:11:15
User entered 'headache'	(b) (4), (b) (6)	22 Sep 2020 20:10:19

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:00:38**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 20:10:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:00:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User closed query 'Per CDM Re-Query: As per previous query, please confirm this is a Solicited AR, and update this field to Yes. Thank you' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 15:34:19
Query 'Per CDM Re-Query: As per previous query, please confirm this is a Solicited AR, and update this field to Yes. Thank you' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 19:16:51
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 19:16:45
User opened query 'Per CDM Re-Query: As per previous query, please confirm this is a Solicited AR, and update this field to Yes. Thank you' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 17:55:10
User closed query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or confirm this is unsolicited event per investigator.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 17:55:10
Query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or confirm this is unsolicited event per investigator.' answered with 'PLEASE SEE START AND STOP DATES FOR AE AS THEY CLEARLY INDICATE THIS EVENT LASTED FOR GREATER THAN 7 DAYS.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 20:55:59
User opened query 'Per DM CLR: Note, this is a solicited event per protocol. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to YES or confirm this is unsolicited event per investigator.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 12:02:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:00:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 20:10:19

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:00:38**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 20:10:19



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:00:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	30 Nov 2020 18:52:45
User closed query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	22 Sep 2020 20:10:27
User closed query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	22 Sep 2020 20:10:27
User entered '28 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 20:10:27
User opened query 'Adverse Event Start Date is before treatment date at Visit 1. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	22 Sep 2020 20:10:19
User opened query 'The Start Date for Adverse Event is prior to ICF Date. Please verify if the dates are correct. If correct, the Adverse Event should be deleted from the AE eCRF and re-recorded in Medical History. Please review and clarify. ' (Site from System).	System	22 Sep 2020 20:10:19
User entered '28 Apr 2020'	(b) (4), (b) (6)	22 Sep 2020 20:10:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:00:38

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User closed query 'Per CDM: Response noted. However Start date is recorded .If Start-time is Unknown then per page 31 of CCGs, 'if start time is within 24 hours of dosing time, then the field must be completed'. Exposure is recorded as 28AUG2020 at 13:29, and AE Start-date is 28AUG2020. Please verify data and update AE Start-time as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 06:56:52
Query 'Per CDM: Response noted. However Start date is recorded .If Start-time is Unknown then per page 31 of CCGs, 'if start time is within 24 hours of dosing time, then the field must be completed'. Exposure is recorded as 28AUG2020 at 13:29, and AE Start-date is 28AUG2020. Please verify data and update AE Start-time as appropriate. Thank you. ' answered with 'updated start time as appropriate to AE start date. Please advise. Thanks! ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:14:52
User entered '13:29' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 16:14:42
User opened query 'Per CDM: Response noted. However Start date is recorded .If Start-time is Unknown then per page 31 of CCGs, 'if start time is within 24 hours of dosing time, then the field must be completed'. Exposure is recorded as 28AUG2020 at 13:29, and AE Start-date is 28AUG2020. Please verify data and update AE Start-time as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 09:27:51
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 09:21:25
Query 'Data is required. Please provide.' answered with 'date is unknown ' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 15:01:17
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Oct 2020 15:01:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:00:38

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 15:01:01
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 20:19:57
User entered '20:48' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 20:19:57
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 20:10:27
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 20:10:19

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:00:38**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:50
User entered '28 Aug 2020 13:29'	System	28 Oct 2020 16:14:42
User entered empty.	System	27 Oct 2020 15:01:01
User entered '28 Aug 2020 20:48'	System	22 Sep 2020 20:19:57
User entered empty.	System	22 Sep 2020 20:10:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:00:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 20:10:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Sep 2020 20:10:27
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 20:10:27
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Sep 2020 20:10:19
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 20:10:19

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:00:38**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '06 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 20:10:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:00:38

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 09:18:44
User closed query 'Per CDM: End time is present for an AE that did not stop within 24 hours after dosing. Per CCG pg.no.32 please consider to remove the End time or else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 09:18:41
Query 'Data is required. Please provide.' answered with 'reconciled' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 15:01:53
Query 'Per CDM: End time is present for an AE that did not stop within 24 hours after dosing. Per CCG pg.no.32 please consider to remove the End time or else clarify. Thank you' answered with 'end date removed' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 15:01:46
User opened query 'Data is required. Please provide.' (Site from System).	System	27 Oct 2020 15:01:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 15:01:01
User opened query 'Per CDM: End time is present for an AE that did not stop within 24 hours after dosing. Per CCG pg.no.32 please consider to remove the End time or else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 16:07:31
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 20:19:57
User entered '13:29' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 20:19:57
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Sep 2020 20:10:27
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 20:10:19

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:00:38**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:50
User entered empty.	System	27 Oct 2020 15:01:01
User entered '06 Sep 2020 13:29'	System	22 Sep 2020 20:19:57
User entered empty.	System	22 Sep 2020 20:10:19



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:00:38**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	22 Sep 2020 20:10:19

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:00:38**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'No (N)'	(b) (4), (b) (6)	22 Sep 2020 20:10:19

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:00:38**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 20:10:19

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:00:38**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 20:10:19

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:00:38**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 20:10:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:00:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 20:10:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:00:38

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 20:10:19

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:00:38**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 20:10:19



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 20:10:19

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:00:38**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 20:10:19

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:00:38**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 20:10:19

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 20:10:19

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:00:38**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	22 Sep 2020 20:10:19

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:00:38**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	22 Sep 2020 20:10:19

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:00:38**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'None (NONE)'	(b) (4), (b) (6)	22 Sep 2020 20:10:19

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:00:38**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 20:10:19



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 23:00:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 18:48:50
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' answered with 'excedrin' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 13:47:56
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 08:50:08
User entered 'I'	(b) (4), (b) (6)	22 Sep 2020 20:10:19

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:00:38**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	22 Sep 2020 20:10:19

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	22 Sep 2020 20:10:19

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:00:38**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 20:10:19

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:00:38**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 20:10:19

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:00:38**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:50
User entered '0'	System	22 Sep 2020 20:10:19

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:00:38**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:50
User entered '0'	System	22 Sep 2020 20:10:19

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 23:00:38**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:52:50



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:38

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note this AE overlaps with AE#6 GENERALIZED PRURITIS and #8 WORSENING OF DERMATOGRAPHIA. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 08:30:11
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
Query 'Per DM CLR: Please note this AE overlaps with AE#6 GENERALIZED PRURITIS and #8 WORSENING OF DERMATOGRAPHIA. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification.' answered with 'separate AEs' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 21:17:53
User opened query 'Per DM CLR: Please note this AE overlaps with AE#6 GENERALIZED PRURITIS and #8 WORSENING OF DERMATOGRAPHIA. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 08:57:01
User closed query 'Per DM CLR: Please provide the specific location of Urticaria (eg, Whole body, back , arms, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 18:58:12
Query 'Per DM CLR: Please provide the specific location of Urticaria (eg, Whole body, back , arms, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'unknown' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 20:51:11
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User opened query 'Per DM CLR: Please provide the specific location of Urticaria (eg, Whole body, back , arms, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	28 Nov 2020 15:11:13

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:38

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Urticaria, LLT: Urticaria - version MedDRA\23.0.	Coder Import (b) (4)	16 Nov 2020 01:06:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	16 Nov 2020 01:06:50
Data point term sent to Coder	System	15 Nov 2020 16:39:55
Coding entries removed.	(b) (4), (b) (6)	15 Nov 2020 16:39:02
User entered 'worsening of URITICARIA' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Nov 2020 16:39:02
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Urticaria, LLT: Urticaria - version MedDRA\23.0.	Coder Import (b) (4)	30 Oct 2020 05:54:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	30 Oct 2020 05:54:58
Data point term sent to Coder	System	29 Oct 2020 21:11:16
Coding entries removed.	(b) (4), (b) (6)	29 Oct 2020 21:10:49
User entered 'Urticaria' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 21:10:49
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash pruritic, LLT: Pruritic rash - version MedDRA\23.0.	Coder Import (b) (4)	17 Oct 2020 09:54:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Oct 2020 09:54:17
Data point term sent to Coder	System	16 Oct 2020 19:20:05
User entered 'intermittent pruritic rash'	(b) (4), (b) (6)	16 Oct 2020 19:19:25

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 19:19:25

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 19:19:25

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Folder: Adverse Events

Form: Adverse Events (5)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 19:19:25

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '21 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Nov 2020 16:39:02
User entered '11 Sep 2020'	(b) (4), (b) (6)	16 Oct 2020 19:19:25

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:38**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 19:19:25

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:38**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 19:19:25



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
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. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:58:24
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'still ongoing' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 20:55:10
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 01:17:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 19:19:25

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:38

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 19:19:25

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:38**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 19:19:25

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:38**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 19:19:25

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:38

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	16 Oct 2020 19:19:25

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 19:19:25

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:38**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 19:19:25

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:38**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 19:19:25



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 19:19:25

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 19:19:25

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:38

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 19:19:25

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:38**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 19:19:25

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:38

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 19:19:25

US3672377

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 19:19:25

US3672377

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 19:19:25

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:38**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 19:19:25



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'Related (RELATED)'	(b) (4), (b) (6)	16 Oct 2020 19:19:25

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	16 Oct 2020 19:19:25

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:38

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:45:36
User closed query 'In AE log source, action taken with study treatment was ticked N/A, then corrected to None. Since the subject was withdrawn from treatment, please tick that box on the AE source log for this AE.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 16:52:26
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
Query 'In AE log source, action taken with study treatment was ticked N/A, then corrected to None. Since the subject was withdrawn from treatment, please tick that box on the AE source log for this AE.'	(b) (4), (b) (6)	08 Apr 2021 21:20:51
answered with 'updated' (Site from CRA).		
User opened query 'In AE log source, action taken with study treatment was ticked N/A, then corrected to None. Since the subject was withdrawn from treatment, please tick that box on the AE source log for this AE.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 13:49:12
DataPoint Un-verified.	(b) (4), (b) (6)	08 Apr 2021 13:48:58
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:42:03
User closed query 'Per CDM: "Investigational Product Withdrawn" have been recorded for AE 5,6,7. However, only one AE should be recorded with IP Withdrawal. Please only record the AE that PI considers the primary AE as IP Withdrawal and ensure the Dosing Discontinuation form has the corresponding AE recorded as well.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 13:45:22
Query 'Per CDM: "Investigational Product Withdrawn" have been recorded for AE 5,6,7. However, only one AE should be recorded with IP Withdrawal. Please only record the AE that PI considers the primary AE as IP Withdrawal and ensure the Dosing Discontinuation form has the corresponding AE recorded as well.'	Patty Howenstine (b) (4)	29 Mar 2021 17:15:18
answered with 'Subject had multiple reasons for discontinuing IP. Why only one allowed?' (Site from DM).	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:38

Action taken with investigational product

Audit	User	Time (GMT)
User opened query 'Per CDM: "Investigational Product Withdrawn" have been recorded for AE 5,6,7. However, only one AE should be recorded with IP Withdrawal. Please only record the AE that PI considers the primary AE as IP Withdrawal and ensure the Dosing Discontinuation form has the corresponding AE recorded as well.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 10:29:24
User closed query 'Per CDM: Action taken with investigational product is entered as 'Not applicable' However, On Dosing Discontinuation form the Primary reason for dosing discontinuation is responded as AE lines 5,6,and 7.Please confirm and update appropriately. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 12:43:15
User closed query 'Action Taken with Investigational System Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).		04 Mar 2021 18:18:40
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System).	System	04 Mar 2021 18:18:40
Query 'Per CDM: Action taken with investigational product is entered as 'Not applicable' However, On Dosing Discontinuation form the Primary reason for dosing discontinuation is responded as AE lines 5,6,and 7.Please confirm and update appropriately. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 18:18:02
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	04 Mar 2021 18:17:51
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 18:17:51
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 18:17:51

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:38

Action taken with investigational product

Audit	User	Time (GMT)
User opened query 'Per CDM: Action taken with investigational product is entered as 'Not applicable' However, On Dosing Discontinuation form the Primary reason for dosing discontinuation is responded as AE lines 5,6,and 7.Please confirm and update appropriately. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 13:08:34
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User closed query 'Action Taken with Investigational System Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	28 Oct 2020 16:16:30
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered by data change (Site from System).	System	28 Oct 2020 16:16:30
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 16:16:30
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	28 Oct 2020 16:11:17
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4), (b) (6)	16 Oct 2020 19:19:25

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:38

None

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Nov 2020 16:39:02
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 19:22:47
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 19:19:25

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Nov 2020 16:39:02
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 19:22:47
User entered '1'	(b) (4), (b) (6)	16 Oct 2020 19:19:25

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 23:00:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 19:19:25



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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:38**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	16 Oct 2020 19:19:25

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:38**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 19:19:25

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:38**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 19:19:25

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:38**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Oct 2020 19:19:25

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 23:00:38**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Oct 2020 19:19:25

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:38**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:05

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:00:38

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:05
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:52:45
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Pruritus NEC, PT: Pruritus, LLT: Generalized pruritus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Nov 2020 16:42:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Nov 2020 16:42:44
Data point term sent to Coder	System	15 Nov 2020 16:41:56
User entered 'generalized pruritis'	(b) (4), (b) (6)	15 Nov 2020 16:41:54

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:05
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Nov 2020 16:41:54



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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:05
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'No (N)'	(b) (4), (b) (6)	15 Nov 2020 16:41:54

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:05
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'No (N)'	(b) (4), (b) (6)	15 Nov 2020 16:41:54

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:05
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '11 Sep 2020'	(b) (4), (b) (6)	15 Nov 2020 16:41:54

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:05
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 16:41:54

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:38**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:05
User entered empty.	System	15 Nov 2020 16:41:54

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:00:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:05
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:43:29
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 18:22:45
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'fixed' (Site from DM).	Patty Howenstine (b) (4)	08 Mar 2021 21:23:19
DataPoint Un-verified.	Patty Howenstine (b) (4)	08 Mar 2021 21:23:07
User entered 'No (N)' reason for change: Data Entry Error	Patty Howenstine (b) (4)	08 Mar 2021 21:23:07
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 10:30:06
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Nov 2020 16:41:54

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:00:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:05
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	08 Apr 2021 13:42:22
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	08 Mar 2021 21:23:28
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	08 Mar 2021 21:23:28
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	08 Mar 2021 21:23:07
DataPoint Un-verified.	Patty Howenstine (b) (4)	08 Mar 2021 21:23:07
User entered '19 Nov 2020' reason for change: Data Entry Error	(b) (4)	08 Mar 2021 21:23:07
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 16:41:54

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:38**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:05
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 16:41:54



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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:00:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:05
User entered empty.	System	15 Nov 2020 16:41:54

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:05
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	15 Nov 2020 16:41:54

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:05
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'No (N)'	(b) (4), (b) (6)	15 Nov 2020 16:41:54

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:05
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 16:41:54

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:05
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 16:41:54

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:05
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 16:41:54

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:00:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:05
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 16:41:54

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:05
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 16:41:54



**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:05
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 16:41:54

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:05
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 16:41:54

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:05
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 16:41:54

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:05
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 16:41:54

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:05
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 16:41:54

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:05
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'Related (RELATED)'	(b) (4), (b) (6)	15 Nov 2020 16:41:54

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:05
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	15 Nov 2020 16:41:54

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:00:38

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:45:21
User closed query 'In AE log source, action taken with study treatment was ticked N/A, then corrected to None. Since the subject was withdrawn from treatment, please tick that box on the AE source log for this AE.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 16:53:18
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
Query 'In AE log source, action taken with study treatment was ticked N/A, then corrected to None. Since the subject was withdrawn from treatment, please tick that box on the AE source log for this AE.'	(b) (4), (b) (6)	08 Apr 2021 21:18:38
answered with 'updated' (Site from CRA).		
User opened query 'In AE log source, action taken with study treatment was ticked N/A, then corrected to None. Since the subject was withdrawn from treatment, please tick that box on the AE source log for this AE.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 13:47:34
DataPoint Un-verified.	(b) (4), (b) (6)	08 Apr 2021 13:47:28
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:43:25
User closed query 'Per CDM: Action taken with investigational product is entered as 'None' However, On Dosing Discontinuation form the Primary reason for dosing discontinuation is responded as AE lines 5,6, and 7 Please confirm and update appropriately.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 10:17:17
Query 'Per CDM: Action taken with investigational product is entered as 'None' However, On Dosing Discontinuation form the Primary reason for dosing discontinuation is responded as AE lines 5,6, and 7 Please confirm and update appropriately.' answered with 'fixed, as did not received 2nd vaccine' (Site from DM).	Patty Howenstine (b) (4)	08 Mar 2021 21:24:25
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4)	08 Mar 2021 21:24:15
DataPoint Un-verified.	Patty Howenstine (b) (4)	08 Mar 2021 21:23:35

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (6)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Patty Howenstine (b) (4)	08 Mar 2021 21:23:35
reason for change: Data Entry Error	(b) (4)	
User opened query 'Per CDM: Action taken with	(b) (4), (b) (6)	21 Dec 2020 13:09:53
investigational product is entered as 'None' However,		
On Dosing Discontinuation form the Primary reason		
for dosing discontinuation is responded as AE lines		
5,6, and 7 Please confirm and update appropriately.'		
(Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'None (NONE)'	(b) (4), (b) (6)	15 Nov 2020 16:41:54

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:38**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:05
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 16:41:54

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:05
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'l'	(b) (4), (b) (6)	15 Nov 2020 16:41:54

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:05
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 16:41:54

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 23:00:38

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:45:25
User closed query 'No outcome is recorded in source for this AE. If this is correct, please enter it there.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 16:53:30
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
Query 'No outcome is recorded in source for this AE. If this is correct, please enter it there.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 21:18:54
User opened query 'No outcome is recorded in source for this AE. If this is correct, please enter it there.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 13:43:20
DataPoint Un-verified.	Patty Howenstine (b) (4)	08 Mar 2021 21:23:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Patty Howenstine (b) (4)	08 Mar 2021 21:23:28
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	15 Nov 2020 16:41:54

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:38**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:05
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 16:41:54

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:05
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 16:41:54

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:05
User entered '0'	System	15 Nov 2020 16:41:54



**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:05
User entered 'I'	System	15 Nov 2020 16:41:54

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:05

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:38**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:13

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:00:38

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:13
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Angioedemas, PT: Angioedema, LLT: Angioedema - version MedDRA\\23.0.	Coder Import (b) (4)	15 Nov 2020 17:36:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Nov 2020 17:36:45
Data point term sent to Coder	System	15 Nov 2020 17:36:14
User entered 'angioedema'	(b) (4), (b) (6)	15 Nov 2020 17:35:36

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:38**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:13
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'No (N)'	(b) (4), (b) (6)	15 Nov 2020 17:35:36

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:38**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:13
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'No (N)'	(b) (4), (b) (6)	15 Nov 2020 17:35:36

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:38**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:13
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'No (N)'	(b) (4), (b) (6)	15 Nov 2020 17:35:36

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:13
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '18 Sep 2020'	(b) (4), (b) (6)	15 Nov 2020 17:35:36



**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:38**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:13
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 17:35:36

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:00:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:13
User entered empty.	System	15 Nov 2020 17:35:36

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:38**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:13
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'No (N)'	(b) (4), (b) (6)	15 Nov 2020 17:35:36

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:38**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:13
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '19 Sep 2020'	(b) (4), (b) (6)	15 Nov 2020 17:35:36

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:38**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:13
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 17:35:36

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:38**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:13
User entered empty.	System	15 Nov 2020 17:35:36

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:38**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:13
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	15 Nov 2020 17:35:36

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:38**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:13
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'No (N)'	(b) (4), (b) (6)	15 Nov 2020 17:35:36



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**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:13
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 17:35:36

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:13
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 17:35:36

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:13
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 17:35:36

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:13
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 17:35:36

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**Form: Adverse Events (7)**

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**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:13
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 17:35:36

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**Form: Adverse Events (7)**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:13
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 17:35:36

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:13
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 17:35:36

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:13
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 17:35:36



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**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:13
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 17:35:36

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:13
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 17:35:36

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:13
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'Related (RELATED)'	(b) (4), (b) (6)	15 Nov 2020 17:35:36

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:13
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	15 Nov 2020 17:35:36

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Aug 2021 23:00:38

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:13
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:45:08
User closed query 'In AE log source, action taken with study treatment was ticked N/A, then corrected to None. Since the subject was withdrawn from treatment, please tick that box on the AE source log for this AE.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 16:54:26
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
Query 'In AE log source, action taken with study treatment was ticked N/A, then corrected to None. Since the subject was withdrawn from treatment, please tick that box on the AE source log for this AE.'	(b) (4), (b) (6)	08 Apr 2021 21:19:26
answered with 'updated' (Site from CRA).		
User opened query 'In AE log source, action taken with study treatment was ticked N/A, then corrected to None. Since the subject was withdrawn from treatment, please tick that box on the AE source log for this AE.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 13:47:13
DataPoint Un-verified.	(b) (4), (b) (6)	08 Apr 2021 13:45:30
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:44:44
User closed query 'Per CDM: Action taken with investigational product is entered as 'None' However, On Dosing Discontinuation form the Primary reason for dosing discontinuation is responded as AE lines 5,6, and 7 Please confirm and update appropriately.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 12:43:36
Query 'Per CDM: Action taken with investigational product is entered as 'None' However, On Dosing Discontinuation form the Primary reason for dosing discontinuation is responded as AE lines 5,6, and 7 Please confirm and update appropriately.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 18:19:29
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 18:19:23
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 18:19:23

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Action taken with investigational product is entered as 'None' However, On Dosing Discontinuation form the Primary reason for dosing discontinuation is responded as AE lines 5,6, and 7 Please confirm and update appropriately.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	21 Dec 2020 13:10:15
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'None (NONE)'	(b) (4), (b) (6)	15 Nov 2020 17:35:36

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:13
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'l'	(b) (4), (b) (6)	15 Nov 2020 17:35:36

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:13
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 17:35:36



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**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:13
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 17:35:36

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:13
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	15 Nov 2020 17:35:36

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**Folder: Adverse Events**

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:13
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 17:35:36

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:13
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 17:35:36

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:38**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:13
User entered '0'	System	15 Nov 2020 17:35:36

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:38**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:13
User entered '0'	System	15 Nov 2020 17:35:36

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Aug 2021 23:00:38**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:13

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:17:50



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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:17:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Mechanical urticaria, LLT: Dermatographia - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 01:07:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 01:07:49
Data point term sent to Coder	System	15 Nov 2020 17:37:22
User entered 'worsening of dermatographia'	(b) (4), (b) (6)	15 Nov 2020 17:37:03

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**Generated On: 11 Aug 2021 23:00:38**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:17:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'No (N)'	(b) (4), (b) (6)	15 Nov 2020 17:37:03

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**Form: Adverse Events (8)**

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:17:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'No (N)'	(b) (4), (b) (6)	15 Nov 2020 17:37:03

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:17:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'No (N)'	(b) (4), (b) (6)	15 Nov 2020 17:37:03

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**Generated On: 11 Aug 2021 23:00:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:17:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '21 Sep 2020'	(b) (4), (b) (6)	15 Nov 2020 17:37:03

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:38**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:17:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 17:37:03

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:38**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:17:50
User entered empty.	System	15 Nov 2020 17:37:03

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:38**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:17:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'No (N)'	(b) (4), (b) (6)	15 Nov 2020 17:37:03



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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:38**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:17:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '04 Nov 2020'	(b) (4), (b) (6)	15 Nov 2020 17:37:03

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:38**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:17:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 17:37:03

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:38**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:17:50
User entered empty.	System	15 Nov 2020 17:37:03

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Folder: Adverse Events

Form: Adverse Events (8)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:17:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:50:06
User closed query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 17:06:35
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 18:33:28
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 18:33:28
Query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification. ' answered with 'added' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 18:32:54
User opened query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 03:52:43
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	15 Nov 2020 17:37:03

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:17:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'No (N)'	(b) (4), (b) (6)	15 Nov 2020 17:37:03

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**Folder: Adverse Events**

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:17:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 17:37:03

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:17:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 17:37:03

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:17:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 17:37:03



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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:17:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 17:37:03

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:38**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:17:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 17:37:03

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:38**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:17:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 17:37:03

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:38**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:17:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 17:37:03

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:38**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:17:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 17:37:03

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:38**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:17:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 17:37:03

US3672377

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:00:38

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:17:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 17:37:03

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:00:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:17:50
User closed query 'Per MM: please clarify why this was considered related to IP.' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 12:11:33
Query 'Per MM: please clarify why this was considered related to IP.' answered with 'temporal relationship' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 18:24:58
User opened query 'Per MM: please clarify why this was considered related to IP.' (Site from DM).	(b) (4), (b) (6)	24 Apr 2021 15:51:08
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'Related (RELATED)'	(b) (4), (b) (6)	15 Nov 2020 17:37:03



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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:38**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:17:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	15 Nov 2020 17:37:03

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:38**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:17:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered 'None (NONE)'	(b) (4), (b) (6)	15 Nov 2020 17:37:03

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:00:38

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:17:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:45:01
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 21:20:07
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#7) recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 17:06:43
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#7) recorded that matches this AE during this timeframe. Please review and update this field.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 18:33:01
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:49
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 18:32:49
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#7) recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 10:30:27
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '1'	(b) (4), (b) (6)	15 Nov 2020 17:37:03

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:00:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:17:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:44:59
User closed query 'AE log source appears to indicate that conmed/additional therapy for this event was originally ticked Yes, then corrected to No, however, here it says conmed was given. Please determine which is correct and ensure AE log and CRF match.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 16:56:33
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
Query 'AE log source appears to indicate that conmed/additional therapy for this event was originally ticked Yes, then corrected to No, however, here it says conmed was given. Please determine which is correct and ensure AE log and CRF match.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 21:20:12
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 21:20:07
User opened query 'AE log source appears to indicate that conmed/additional therapy for this event was originally ticked Yes, then corrected to No, however, here it says conmed was given. Please determine which is correct and ensure AE log and CRF match.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 13:51:45
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 18:32:49
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 18:32:49
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 17:37:03

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:38**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:17:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered '0'	(b) (4), (b) (6)	15 Nov 2020 17:37:03

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 11 Aug 2021 23:00:38

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:17:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Nov 2020 17:37:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Nov 2020 17:37:38
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4), (b) (6)	15 Nov 2020 17:37:38
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Nov 2020 17:37:03
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 17:37:03

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:38**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:17:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 17:37:03

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**Folder: Adverse Events**

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:17:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:52:45
User entered empty.	(b) (4), (b) (6)	15 Nov 2020 17:37:03



**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:38**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:17:50
User entered '0'	System	15 Nov 2020 17:37:03

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:38**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:17:50
User entered '0'	System	15 Nov 2020 17:37:03

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 11 Aug 2021 23:00:38**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:17:50

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 23:00:38**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:23

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 23:00:38

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:53:12
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Dental and oral soft tissue infections, PT: Tooth infection, LLT: Tooth infection - version MedDRA\\23.0.	Coder Import (b) (4)	05 Apr 2021 15:01:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Apr 2021 15:01:27
Data point term sent to Coder	System	05 Apr 2021 15:00:12
User entered 'Tooth infection'	(b) (4), (b) (6)	05 Apr 2021 15:00:04

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 23:00:38**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:53:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 15:00:04

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 23:00:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:53:12
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 15:00:04

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 23:00:38**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:53:12
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 15:00:04



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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 23:00:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:53:12
User entered '14 Mar 2021'	(b) (4), (b) (6)	05 Apr 2021 15:00:04

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 23:00:38**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:53:12
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 15:00:04

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 23:00:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:23
User entered empty.	System	05 Apr 2021 15:00:04

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 23:00:38**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:53:12
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 15:00:04

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Folder: Adverse Events

Form: Adverse Events (10)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:53:12
User entered '16 Mar 2021'	(b) (4), (b) (6)	05 Apr 2021 15:00:04

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 23:00:38**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:53:12
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 15:00:04

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 23:00:38**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:23
User entered empty.	System	05 Apr 2021 15:00:04

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 23:00:38

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	08 Apr 2021 13:53:12
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	05 Apr 2021 15:00:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Apr 2021 15:00:23
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	System	05 Apr 2021 15:00:23
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	05 Apr 2021 15:00:04
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 15:00:04



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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 23:00:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:53:12
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 15:00:04

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 23:00:38**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:53:12
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 15:00:04

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 23:00:38**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:53:12
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 15:00:04

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 23:00:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:53:12
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 15:00:04

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 23:00:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:53:12
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 15:00:04

US3672377

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 23:00:38

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:53:12
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 15:00:04

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 23:00:38**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:53:12
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 15:00:04

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 23:00:38**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:53:12
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 15:00:04



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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 23:00:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	08 Apr 2021 13:53:12
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 15:00:04

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 23:00:38**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:53:12
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 15:00:04

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 23:00:38

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:53:12
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 15:00:04

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 23:00:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	08 Apr 2021 13:53:12
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	05 Apr 2021 15:00:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Apr 2021 15:00:23
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	05 Apr 2021 15:00:23
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	05 Apr 2021 15:00:04
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 15:00:04

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 23:00:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	08 Apr 2021 13:53:12
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 15:00:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Apr 2021 15:00:23
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 15:00:23
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 15:00:04
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 15:00:04

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 23:00:38

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:23
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:44:45
User closed query 'No boxes are ticked for this on the AE source. If this is correct, please enter it on the AE source log.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 19:44:43
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
Query 'No boxes are ticked for this on the AE source. If this is correct, please enter it on the AE source log.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 21:21:13
User opened query 'No boxes are ticked for this on the AE source. If this is correct, please enter it on the AE source log.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 13:53:52
DataPoint Un-verified.	(b) (4), (b) (6)	08 Apr 2021 13:53:19
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:53:12
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 15:00:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Apr 2021 15:00:23
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 15:00:23
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Apr 2021 15:00:04
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 15:00:04

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 23:00:38**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:53:12
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 15:00:04

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 23:00:38**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:53:12
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 15:00:04



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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 23:00:38**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:53:12
User entered 'l'	(b) (4), (b) (6)	05 Apr 2021 15:00:04

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 23:00:38**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:53:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	05 Apr 2021 15:00:04

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 11 Aug 2021 23:00:38

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:53:12
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 15:00:04

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 23:00:38**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:53:12
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 15:00:04

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 23:00:38**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:23
User entered '0'	System	05 Apr 2021 15:00:04

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 23:00:38**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:23
User entered 'I'	System	05 Apr 2021 15:00:04

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**Folder: Adverse Events**

**Form: Adverse Events (10)**

**Generated On: 11 Aug 2021 23:00:38**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:23

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**Folder: Adverse Events**

**Form: Adverse Events (11)**

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27



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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 13:54:29
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Procedural pain, LLT: Post procedural pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Apr 2021 15:03:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Apr 2021 15:03:57
Data point term sent to Coder	System	05 Apr 2021 15:02:16
User entered 'Pain secondary to tooth extraction'	(b) (4), (b) (6)	05 Apr 2021 15:02:14

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 23:00:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:44:26
User closed query 'No boxes are ticked for this on the AE source. If this is correct, please enter it on the AE source log. ' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 19:44:19
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
Query 'No boxes are ticked for this on the AE source. If this is correct, please enter it on the AE source log. ' answered with 'correct' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 21:21:39
User opened query 'No boxes are ticked for this on the AE source. If this is correct, please enter it on the AE source log. ' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 13:54:40
DataPoint Un-verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:35
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:29
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 15:02:14

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Folder: Adverse Events

Form: Adverse Events (11)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:44:24
User closed query 'No boxes are ticked for this on the AE source. If this is correct, please enter it on the AE source log. ' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 19:44:22
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
Query 'No boxes are ticked for this on the AE source. If this is correct, please enter it on the AE source log. ' answered with 'correct' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 21:21:43
User opened query 'No boxes are ticked for this on the AE source. If this is correct, please enter it on the AE source log. ' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 13:54:51
DataPoint Un-verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:46
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:29
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 15:02:14

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**Folder: Adverse Events**

**Form: Adverse Events (11)**

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:54:29
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 15:02:14

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**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 23:00:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:29
User entered '16 Mar 2021'	(b) (4), (b) (6)	05 Apr 2021 15:02:14

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**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 23:00:38**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:54:29
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 15:02:14

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 23:00:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User entered empty.	System	05 Apr 2021 15:02:14

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 23:00:38**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:29
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 15:02:14



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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 23:00:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:29
User entered '17 Mar 2021'	(b) (4), (b) (6)	05 Apr 2021 15:02:14

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 23:00:38**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:29
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 15:02:14

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 23:00:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User entered empty.	System	05 Apr 2021 15:02:14

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 23:00:38**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:29
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	05 Apr 2021 15:02:14

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 23:00:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:29
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 15:02:14

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 23:00:38**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:54:29
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 15:02:14

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 23:00:38

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:29
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 15:02:14

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 23:00:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:54:29
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 15:02:14



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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 23:00:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:54:29
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 15:02:14

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 23:00:38

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:29
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 15:02:14

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**Folder: Adverse Events**

**Form: Adverse Events (11)**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:29
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 15:02:14

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:29
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 15:02:14

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Folder: Adverse Events

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:29
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 15:02:14

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**Folder: Adverse Events**

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:29
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 15:02:14

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**Folder: Adverse Events**

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:29
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 15:02:14

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**Folder: Adverse Events**

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:29
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Apr 2021 15:02:14



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**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 23:00:38**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:29
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Apr 2021 15:02:14

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Folder: Adverse Events

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:29
User entered 'None (NONE)'	(b) (4), (b) (6)	05 Apr 2021 15:02:14

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**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 23:00:38**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:54:29
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 15:02:14

US3672377

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 11 Aug 2021 23:00:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:54:29
User entered 'l'	(b) (4), (b) (6)	05 Apr 2021 15:02:14

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 23:00:38**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:29
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 15:02:14

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 23:00:38**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:54:29
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	05 Apr 2021 15:02:14

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 23:00:38**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:29
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 15:02:14

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 23:00:38**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:54:29
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 15:02:14



**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 23:00:38**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User entered '0'	System	05 Apr 2021 15:02:14

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 23:00:38**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27
User entered '0'	System	05 Apr 2021 15:02:14

**US3672377**

**Folder: Adverse Events**

**Form: Adverse Events (11)**

**Generated On: 11 Aug 2021 23:00:38**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:53:27

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 23:00:38

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:06:38
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
User closed query 'Per DM CLR: Per Diary Dose 1 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 18:25:10
Query 'Per DM CLR: Per Diary Dose 1 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'took meds for HA on 8/28/2020 to 9/06/2020' (Site from DM).	Patty Howenstine (b) (4) (b) (4)	08 Mar 2021 21:30:23
User opened query 'Per DM CLR: Per Diary Dose 1 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 15:08:27
Query 'Per DM CLR: Per Diary Dose 1 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' canceled (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 04:56:19

US3672377

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 11 Aug 2021 23:00:38**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Per Diary Dose 1 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever &gt; 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 07:44:56
DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 17:32:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 15:07:17

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:00:38

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: AMFETAMINE ASPARTATE;AMFETAMINE SULFATE;DEXAMFETAMINE SACCHARATE;DEXAMFETAMINE SULFATE, PRODUCTSYNONYM: ADDERALL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 15:10:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	01 Sep 2020 15:09:27
User entered 'ADDERALL'	(b) (4), (b) (6)	01 Sep 2020 15:08:34

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:00:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 15:08:34

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:00:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'ADHD'	(b) (4), (b) (6)	01 Sep 2020 15:08:34



US3672377

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:00:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered '30'	(b) (4), (b) (6)	01 Sep 2020 15:08:34

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:00:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Sep 2020 15:08:34

US3672377

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:00:38**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 15:08:34

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:00:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:51:43
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 15:06:14
User entered 'twice daily (BID)' reason for change:	(b) (4), (b) (6)	27 Oct 2020 15:06:14
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'other (OTHER)'	(b) (4), (b) (6)	01 Sep 2020 15:08:34

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:00:38

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:51:43
User closed query 'Per DM CLR: Please review "Other Frequency" as there is an available option for "twice daily" in the listed choices for frequency. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 07:33:49
Query 'Per DM CLR: Please review "Other Frequency" as there is an available option for "twice daily" in the listed choices for frequency. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' answered with 'reconciled data ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 15:06:21
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 15:06:14
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 15:06:14
User opened query 'Per DM CLR: Please review "Other Frequency" as there is an available option for "twice daily" in the listed choices for frequency. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 06:51:44
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'BID'	(b) (4), (b) (6)	01 Sep 2020 15:08:34

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:00:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Sep 2020 15:08:34

US3672377

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:00:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 15:08:34

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:00:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered '11 Aug 2020'	(b) (4), (b) (6)	01 Sep 2020 15:08:34



US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:00:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 15:08:34

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 23:00:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 15:08:34

US3672377

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:00:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 15:08:34

US3672377

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:00:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 15:08:34

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:00:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	27 Oct 2020 15:06:14
User entered empty.	System	01 Sep 2020 15:08:34

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:00:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 15:06:14
User entered empty.	System	01 Sep 2020 15:08:34

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 23:00:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Oct 2020 15:06:14
User entered empty.	System	01 Sep 2020 15:08:34

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:00:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 15:11:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 15:11:45
Data point term sent to Coder	System	01 Sep 2020 15:10:29
User entered 'OMEPRAZOLE'	(b) (4), (b) (6)	01 Sep 2020 15:09:30



US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:00:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 15:09:30

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:00:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'GERD'	(b) (4), (b) (6)	01 Sep 2020 15:09:30

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:00:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered '40'	(b) (4), (b) (6)	01 Sep 2020 15:09:30

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:00:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Sep 2020 15:09:30

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:00:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 15:09:30

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:00:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'as needed (PRN)'	(b) (4), (b) (6)	01 Sep 2020 15:09:30

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:00:38

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 15:09:30

US3672377

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 23:00:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Sep 2020 15:09:30



US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:00:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 15:09:30

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:00:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'UN UNK 2019'	(b) (4), (b) (6)	01 Sep 2020 15:09:30

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:00:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 15:09:30

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 23:00:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 15:09:30

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:00:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 15:09:30

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 23:00:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 15:09:30

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 23:00:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 15:09:30

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 23:00:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 15:09:30



**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 23:00:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 15:09:30

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:00:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS, PRODUCT: MEDROXYPROGESTERONE ACETATE, PRODUCTSYNONYM: PROVERA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 03:33:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 03:33:43
Data point term sent to Coder	System	27 Oct 2020 15:06:46
Coding entries removed.	(b) (4), (b) (6)	27 Oct 2020 15:06:41
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS, PRODUCT: MEDROXYPROGESTERONE ACETATE, PRODUCTSYNONYM: DEPO PROVERA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 15:30:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 15:30:52
Data point term sent to Coder	System	01 Sep 2020 15:11:33
User entered 'DEPOT PROVERA'	(b) (4), (b) (6)	01 Sep 2020 15:11:27

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:00:38

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:46:10
User closed query "'Other' is ticked for this on the AE source. If prophylaxis is correct, please enter it on the AE source log. ' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 19:46:07
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
Query "'Other' is ticked for this on the AE source. If prophylaxis is correct, please enter it on the AE source log. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 21:22:26
User opened query "'Other' is ticked for this on the AE source. If prophylaxis is correct, please enter it on the AE source log. ' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 13:57:45
User closed query 'Per DM CLR: Indication reflect prophylaxis, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 18:26:08
Query 'Per DM CLR: Indication reflect prophylaxis, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate. ' answered with 'updated' (Site from DM).	Patty Howenstine (b) (4)	08 Mar 2021 21:26:15
DataPoint Un-verified.	Patty Howenstine (b) (4)	08 Mar 2021 21:26:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Patty Howenstine (b) (4)	08 Mar 2021 21:26:09
User opened query 'Per DM CLR: Indication reflect prophylaxis, so please verify if field 'Prophylaxis' should be updated to 'Yes'. If yes, please update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 17:56:53
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 15:11:27

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:00:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'BIRTH CONTROL'	(b) (4), (b) (6)	01 Sep 2020 15:11:27

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:00:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'I'	(b) (4), (b) (6)	01 Sep 2020 15:11:27

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:00:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'Other (OTHER)'	(b) (4), (b) (6)	01 Sep 2020 15:11:27

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:00:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'INJECTION'	(b) (4), (b) (6)	01 Sep 2020 15:11:27

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:00:38**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'other (OTHER)'	(b) (4), (b) (6)	01 Sep 2020 15:11:27



US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:00:38

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered '9 1/2 WEEKS'	(b) (4), (b) (6)	01 Sep 2020 15:11:27

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:00:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:51:43
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 15:06:41
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	27 Oct 2020 15:06:41
reason for change: Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'Other (OTHER)'	(b) (4), (b) (6)	01 Sep 2020 15:11:27

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:00:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:51:43
User closed query 'Per DM CLR: Please review "Other Route" as there is an available option for "Intramuscular" in the listed choices for route. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 22:24:21
Query 'Per DM CLR: Please review "Other Route" as there is an available option for "Intramuscular" in the listed choices for route. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' answered with 'reconciled ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 15:06:48
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 15:06:41
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 15:06:41
User opened query 'Per DM CLR: Please review "Other Route" as there is an available option for "Intramuscular" in the listed choices for route. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 00:26:56
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'IM'	(b) (4), (b) (6)	01 Sep 2020 15:11:27

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:00:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'UN Oct 2019'	(b) (4), (b) (6)	01 Sep 2020 15:11:27

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:00:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 15:11:27

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:00:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 15:11:27

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 23:00:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 15:11:27

US3672377

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:00:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 15:11:27



**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:00:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 15:11:27

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:00:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 15:11:27

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 23:00:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 15:11:27

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:00:38

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:23
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:46:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN [ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 09:44:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 09:44:00
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	12 Apr 2021 20:45:24
Data point term sent to Coder	System	12 Apr 2021 13:47:15
User closed query 'CDM Coding : Per query response, please update the drug name as EXCEDRIN (UNKNOWN) in the drug name field. Please make changes accordingly. Thank you.' (Site from System).	System	12 Apr 2021 13:47:06
Query 'CDM Coding : Per query response, please update the drug name as EXCEDRIN (UNKNOWN) in the drug name field. Please make changes accordingly. Thank you.' answered with 'Updated ' (Site from System).	(b) (4), (b) (6)	12 Apr 2021 13:47:06
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 13:46:54
Coding entries removed.	(b) (4), (b) (6)	12 Apr 2021 13:46:54
Signature has been broken.	(b) (4), (b) (6)	12 Apr 2021 13:46:54
User entered 'EXCEDRIN (UNKNOWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 13:46:54
User opened query 'CDM Coding : Per query response, please update the drug name as EXCEDRIN (UNKNOWN) in the drug name field. Please make changes accordingly. Thank you.' (Site from System).	Coder Import (b) (4) (b) (4)	09 Apr 2021 11:43:33

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:00:38

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
Data point term sent to Coder	(b) (4)	
User closed query 'For coding purposes, references indicate different formulations for EXCEDRIN. Please provide generic ingredients, complete, accurate trade name and update the term with your response' (Site from System).	System	08 Apr 2021 21:23:08
Query 'For coding purposes, references indicate different formulations for EXCEDRIN. Please provide generic ingredients, complete, accurate trade name and update the term with your response' answered with 'unknown' (Site from System).	System	08 Apr 2021 21:22:48
User opened query 'For coding purposes, references indicate different formulations for EXCEDRIN. Please provide generic ingredients, complete, accurate trade name and update the term with your response' (Site from System).	(b) (4), (b) (6)	08 Apr 2021 21:22:48
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN [ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 15:00:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	14 Sep 2020 14:59:43
User entered 'excedrin'	(b) (4), (b) (6)	14 Sep 2020 14:59:31

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:00:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	08 Oct 2020 17:09:09
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 14:59:31

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:00:38**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'headaches'	(b) (4), (b) (6)	14 Sep 2020 14:59:31

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:00:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	30 Nov 2020 18:51:43
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)	28 Oct 2020 22:23:53
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 'reconciled data' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 15:07:31
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 15:07:24
User entered '250' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 15:07:24
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 05:05:12
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered '1'	(b) (4), (b) (6)	14 Sep 2020 14:59:31



US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:00:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	30 Nov 2020 18:51:43
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 15:07:24
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 15:07:24
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	14 Sep 2020 14:59:31

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:00:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	08 Oct 2020 17:09:09
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 14:59:31

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:00:38**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	08 Oct 2020 17:09:09
User entered 'as needed (PRN)'	(b) (4), (b) (6)	14 Sep 2020 14:59:31

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:00:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	08 Oct 2020 17:09:09
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 14:59:31

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:00:38**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	08 Oct 2020 17:09:09
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Sep 2020 14:59:31

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:00:38**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	08 Oct 2020 17:09:09
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 14:59:31

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:00:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	08 Oct 2020 17:09:09
User entered '28 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 20:05:00
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	14 Sep 2020 14:59:40
User entered '07 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Sep 2020 14:59:40
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	14 Sep 2020 14:59:31
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 14:59:31

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:00:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	08 Oct 2020 17:09:09
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 14:59:31



**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:00:38**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	08 Oct 2020 17:09:09
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 20:05:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 14:59:31

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:00:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	08 Oct 2020 17:09:09
User entered '06 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Sep 2020 20:05:00
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 14:59:31

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 23:00:38

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	30 Nov 2020 18:51:43
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = NO. However, associated condition is a Solicited AE. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 22:25:17
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = NO. However, associated condition is a Solicited AE. Review and update entry as appropriate.' answered with 'reconciled data ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 15:08:59
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 15:08:52
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 15:08:52
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = NO. However, associated condition is a Solicited AE. Review and update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 12:03:07
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 14:59:31

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:00:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:23
User entered empty.	System	14 Sep 2020 14:59:31

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:00:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:23
User entered empty.	System	14 Sep 2020 14:59:31

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 23:00:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:23
User entered empty.	System	14 Sep 2020 14:59:31

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:00:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:25
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 17:09:09
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 15:08:01
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 Sep 2020 15:08:01
Data point term sent to Coder	System	14 Sep 2020 15:07:06
User entered 'Amoxicillin'	(b) (4), (b) (6)	14 Sep 2020 15:06:19

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 23:00:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:25
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	08 Oct 2020 17:09:09
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 15:06:19



**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 23:00:38**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:25
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'Tooth Infection'	(b) (4), (b) (6)	14 Sep 2020 15:06:19

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:00:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:25
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered '500'	(b) (4), (b) (6)	14 Sep 2020 15:06:19

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 23:00:38**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:25
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'mg (mg)'	(b) (4), (b) (6)	14 Sep 2020 15:06:19

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 23:00:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:25
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	08 Oct 2020 17:09:09
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 15:06:19

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 23:00:38**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:25
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'three times daily (TID)'	(b) (4), (b) (6)	14 Sep 2020 15:06:19

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:00:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:25
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	08 Oct 2020 17:09:09
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 15:06:19

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 23:00:38**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:25
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	08 Oct 2020 17:09:09
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Sep 2020 15:06:19

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:00:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:25
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	08 Oct 2020 17:09:09
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 15:06:19



**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 23:00:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:25
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	08 Oct 2020 17:09:09
User entered '09 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 15:06:19

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 23:00:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:25
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 15:06:19

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:00:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:25
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	20 Oct 2020 17:49:17
User closed query 'Per source, this is not ongoing. The end date is 19Sep2020. Please verify and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	20 Oct 2020 17:49:15
Query 'Per source, this is not ongoing. The end date is 19Sep2020. Please verify and update accordingly. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	16 Oct 2020 19:20:37
DataPoint Un-verified.	(b) (4), (b) (6)	16 Oct 2020 19:20:32
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 19:20:32
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User opened query 'Per source, this is not ongoing. The end date is 19Sep2020. Please verify and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	08 Oct 2020 17:07:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 15:06:19

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 23:00:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:25
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	20 Oct 2020 17:49:20
DataPoint Un-verified.	(b) (4), (b) (6)	16 Oct 2020 19:20:32
User entered '19 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 19:20:32
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 15:06:19

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 23:00:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:25
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	08 Oct 2020 17:09:09
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 15:06:19

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 23:00:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:25
User entered '3'	System	14 Sep 2020 15:06:19

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 23:00:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:25
User entered '1'	System	14 Sep 2020 15:06:19

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 23:00:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:25
User entered '804 (804)'	System	14 Sep 2020 15:06:19



US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:00:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	08 Oct 2020 17:09:09
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Sep 2020 15:08:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	14 Sep 2020 15:08:00
Data point term sent to Coder	System	14 Sep 2020 15:07:06
User entered 'Hydrocodone/Acetaminophen'	(b) (4), (b) (6)	14 Sep 2020 15:07:00

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	08 Oct 2020 17:09:09
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 15:07:00

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'Tooth Infection'	(b) (4), (b) (6)	14 Sep 2020 15:07:00

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered '5-325'	(b) (4), (b) (6)	14 Sep 2020 15:07:00

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:00:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'mg (mg)'	(b) (4), (b) (6)	14 Sep 2020 15:07:00

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:00:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	08 Oct 2020 17:09:09
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 15:07:00

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:00:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'four times daily (QID)'	(b) (4), (b) (6)	14 Sep 2020 15:07:00

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:00:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 15:07:00



**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Sep 2020 15:07:00

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 23:00:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	08 Oct 2020 17:09:09
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 15:07:00

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered '09 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 15:07:00

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered '0'	(b) (4), (b) (6)	14 Sep 2020 15:07:00

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 15:07:00

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:00:38**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered '13 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 15:07:00

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:27
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	08 Oct 2020 17:09:09
User entered 'No (N)'	(b) (4), (b) (6)	14 Sep 2020 15:07:00

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:27
User entered '4'	System	14 Sep 2020 15:07:00



**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:27
User entered '1'	System	14 Sep 2020 15:07:00

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 23:00:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:27
User entered '804 (804)'	System	14 Sep 2020 15:07:00

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:00:38

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:29
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
User closed query 'Per DM CLR: Please review if this Conmed was given for the AE #8. If so, please note "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Kindly review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please review if this Conmed was given for the AE #8. If so, please note "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Kindly review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.' answered with 'does reflect on AE' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 18:23:56
User opened query 'Per DM CLR: Please review if this Conmed was given for the AE #8. If so, please note "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Kindly review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification.' (Site from DM).	Patty Howenstine (b) (4)	08 Mar 2021 21:27:13
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\202003.	(b) (4), (b) (6)	30 Jan 2021 19:00:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Nov 2020 14:58:01
Data point term sent to Coder Coding entries removed.	(b) (4)	
	System	15 Nov 2020 16:45:01
	(b) (4), (b) (6)	15 Nov 2020 16:44:42

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:00:38

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Oct 2020 23:19:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Oct 2020 23:19:44
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:09:09
Data point term sent to Coder	System	08 Oct 2020 15:42:46
Query 'CDM-Coding: The trade name can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term.	Coder Import (b) (4)	08 Oct 2020 15:42:32
' canceled (Site from System).		
User opened query 'CDM-Coding: The trade name can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term.	Coder Import (b) (4)	02 Oct 2020 08:32:37
' (Site from System).		
Data point term sent to Coder	System	01 Oct 2020 18:42:15
User entered 'ZYRTEC'	(b) (4), (b) (6)	01 Oct 2020 18:41:42

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:00:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:29
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	08 Oct 2020 17:09:09
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 18:41:42

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:00:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:29
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:51:43
DataPoint Un-verified.	(b) (4), (b) (6)	15 Nov 2020 16:44:42
User entered 'worsening of DERMATOGRAPHIA'	(b) (4), (b) (6)	15 Nov 2020 16:44:42
reason for change: Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'DERMATOGRAPHIA'	(b) (4), (b) (6)	01 Oct 2020 18:41:42

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:00:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:46:29
User closed query 'If this is correct, please update the source conmed log to match.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 16:58:08
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
Query 'If this is correct, please update the source conmed log to match.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 21:23:11
User opened query 'If this is correct, please update the source conmed log to match.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 14:15:30
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)	10 Mar 2021 18:27:46
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' (Site from DM).	Patty Howenstine (b) (4)	08 Mar 2021 21:27:58
DataPoint Un-verified.	Patty Howenstine (b) (4)	08 Mar 2021 21:27:34
User entered '10' reason for change: Data Entry Error	Patty Howenstine (b) (4)	08 Mar 2021 21:27:34
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)	18 Nov 2020 07:50:51
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered '1'	(b) (4), (b) (6)	01 Oct 2020 18:41:42

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:00:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:47:59
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Un-verified.	(b) (4) Patty Howenstine (b) (4)	08 Mar 2021 21:27:34
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4) Patty Howenstine (b) (4)	08 Mar 2021 21:27:34
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	01 Oct 2020 18:41:42



US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:00:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:29
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	08 Oct 2020 17:09:09
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:41:42

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:00:38**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:29
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'as needed (PRN)'	(b) (4), (b) (6)	01 Oct 2020 18:41:42

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:00:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:29
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:41:42

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:00:38**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:29
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Oct 2020 18:41:42

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:00:38**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:29
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	08 Oct 2020 17:09:09
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:41:42

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:00:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:46:31
User closed query ' If this is correct, please update the source conmed log to match.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 16:57:50
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
Query ' If this is correct, please update the source conmed log to match.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 21:24:01
User opened query ' If this is correct, please update the source conmed log to match.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 14:16:06
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Else, confirm CM was given on UN UNK 2019. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 16:42:36
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Else, confirm CM was given on UN UNK 2019. ' answered with 'updated' (Site from DM).	Patty Howenstine (b) (4)	29 Mar 2021 18:05:36
DataPoint Un-verified.	Patty Howenstine (b) (4)	29 Mar 2021 18:05:21
User entered '21 Sep 2020' reason for change: Data Entry Error	Patty Howenstine (b) (4)	29 Mar 2021 18:05:21
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Else, confirm CM was given on UN UNK 2019. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 08:49:28
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'UN UNK 2019'	(b) (4), (b) (6)	01 Oct 2020 18:41:42

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:00:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:29
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	08 Oct 2020 17:09:09
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 18:41:42

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:00:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:46:33
User closed query ' If this is correct, please update the source conmed log to match.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 16:58:23
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
Query ' If this is correct, please update the source conmed log to match.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 21:24:04
User opened query ' If this is correct, please update the source conmed log to match.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 14:16:26
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 04:52:21
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'updated end date' (Site from DM).	Patty Howenstine (b) (4)	08 Mar 2021 21:28:16
DataPoint Un-verified.	Patty Howenstine (b) (4)	08 Mar 2021 21:28:08
User entered 'No (N)' reason for change: Data Entry Error	Patty Howenstine (b) (4)	08 Mar 2021 21:28:08
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	30 Jan 2021 19:01:48
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 18:41:42



US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 23:00:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:29
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:46:35
User closed query ' If this is correct, please update the source conmed log to match.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 16:58:45
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
Query ' If this is correct, please update the source conmed log to match.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 21:24:07
User opened query ' If this is correct, please update the source conmed log to match.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 14:16:31
DataPoint Un-verified.	Patty Howenstine (b) (4)	08 Mar 2021 21:28:08
User entered '04 Nov 2020' reason for change: Data Entry Error	(b) (4)	08 Mar 2021 21:28:08
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:41:42

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:00:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:29
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 18:41:42

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:00:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:29
User entered empty.	System	01 Oct 2020 18:41:42

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:00:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:29
User entered empty.	System	01 Oct 2020 18:41:42

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 23:00:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:29
User entered empty.	System	01 Oct 2020 18:41:42

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:00:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC., ATC: ANTIPRURITICS, INCL. ANTIHISTAMINES, ANESTHETICS, ETC., ATC: ANTIHISTAMINES FOR TOPICAL USE, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 20:08:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 20:08:53
Data point term sent to Coder	System	01 Oct 2020 18:43:26
User entered 'BENADRYL'	(b) (4), (b) (6)	01 Oct 2020 18:42:44

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:00:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 18:42:44

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:00:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'DERMATOGRAPHIA'	(b) (4), (b) (6)	01 Oct 2020 18:42:44



US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:00:38

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:46:40
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
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) (4), (b) (6)	10 Mar 2021 19:54:31
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 actual dosage' (Site from DM).	Patty Howenstine (b) (4) (b) (4)	08 Mar 2021 21:28:43
DataPoint Un-verified.	Patty Howenstine (b) (4) (b) (4)	08 Mar 2021 21:28:34
User entered '25' reason for change: Data Entry Error	Patty Howenstine (b) (4) (b) (4)	08 Mar 2021 21:28:34
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)	18 Nov 2020 07:50:22
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered '1'	(b) (4), (b) (6)	01 Oct 2020 18:42:44

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:00:38

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:46:45
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Un-verified.	Patty Howenstine (b) (4)	08 Mar 2021 21:28:34
User entered 'mg (mg)' reason for change: Data Entry Error	Patty Howenstine (b) (4)	08 Mar 2021 21:28:34
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	01 Oct 2020 18:42:44

US3672377

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 23:00:38**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:42:44

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:00:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'as needed (PRN)'	(b) (4), (b) (6)	01 Oct 2020 18:42:44

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:00:38

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:42:44

US3672377

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 23:00:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Oct 2020 18:42:44

US3672377

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 23:00:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:42:44

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:00:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'UN UNK 2019'	(b) (4), (b) (6)	01 Oct 2020 18:42:44



US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:00:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 18:42:44

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 23:00:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 18:42:44

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 23:00:38**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 18:42:44

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 23:00:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 17:09:09
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 18:42:44

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 23:00:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 18:42:44

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 23:00:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 18:42:44

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 23:00:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 18:42:44

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:00:38

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:34
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:51:43
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: LINCOSAMIDES, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Oct 2020 09:53:23
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Oct 2020 09:53:23
	(b) (4)	
Data point term sent to Coder	System	16 Oct 2020 19:22:07
User entered 'clindamycin'	(b) (4), (b) (6)	16 Oct 2020 19:22:04



US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:00:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:34
User closed query 'Please correct this on the AE source log as it now says both AE and prophylaxis.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 19:46:54
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:46:53
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
Query 'Please correct this on the AE source log as it now says both AE and prophylaxis.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 21:24:37
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 21:24:32
User opened query 'Please correct this on the AE source log as it now says both AE and prophylaxis.' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 14:17:16
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 19:56:08
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' answered with 'updated' (Site from DM).	Patty Howenstine (b) (4)	08 Mar 2021 21:29:07
DataPoint Un-verified.	(b) (4)	08 Mar 2021 21:29:02
User entered 'No (N)' reason for change: Data Entry Error	Patty Howenstine (b) (4)	08 Mar 2021 21:29:02
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the AE eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 17:57:05
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 19:22:04

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**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:00:38**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:34
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered 'tooth infection'	(b) (4), (b) (6)	16 Oct 2020 19:22:04

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:00:38**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:34
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered '300'	(b) (4), (b) (6)	16 Oct 2020 19:22:04

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:00:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:34
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered 'mg (mg)'	(b) (4), (b) (6)	16 Oct 2020 19:22:04

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:00:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:34
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 19:22:04

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:00:38**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:34
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered 'four times daily (QID)'	(b) (4), (b) (6)	16 Oct 2020 19:22:04

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:00:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:34
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 19:22:04

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:00:38**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:34
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	16 Oct 2020 19:22:04



**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:00:38**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:34
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 19:22:04

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:00:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:34
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered '08 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 19:22:04

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:00:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:34
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered '0'	(b) (4), (b) (6)	16 Oct 2020 19:22:04

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:00:38**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:34
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	29 Oct 2020 21:13:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 19:22:04

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:00:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:34
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered '17 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 21:13:03
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 19:22:04

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 23:00:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:34
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 19:22:04

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:00:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:34
User entered '4'	System	16 Oct 2020 19:22:04

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:00:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:34
User entered '1'	System	16 Oct 2020 19:22:04



**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 23:00:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:34
User entered '804 (804)'	System	16 Oct 2020 19:22:04

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 23:00:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Nov 2020 18:53:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Nov 2020 18:53:16
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	30 Nov 2020 18:51:45 30 Nov 2020 18:51:43
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 21:13:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 21:13:43
Data point term sent to Coder User entered 'Allegra'	System (b) (4), (b) (6)	29 Oct 2020 21:12:19 29 Oct 2020 21:11:58

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 23:00:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 21:11:58

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 23:00:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered 'Urticaria'	(b) (4), (b) (6)	29 Oct 2020 21:11:58

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 23:00:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered '180'	(b) (4), (b) (6)	29 Oct 2020 21:11:58

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 23:00:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered 'mg (mg)'	(b) (4), (b) (6)	29 Oct 2020 21:11:58

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 23:00:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:11:58

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 23:00:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered 'twice daily (BID)'	(b) (4), (b) (6)	29 Oct 2020 21:11:58



US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 23:00:38

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:11:58

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 23:00:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	29 Oct 2020 21:11:58

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 23:00:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:11:58

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 23:00:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered '19 Oct 2020'	(b) (4), (b) (6)	29 Oct 2020 21:11:58

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 23:00:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered '0'	(b) (4), (b) (6)	29 Oct 2020 21:11:58

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 23:00:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 21:11:58

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 23:00:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:11:58

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 23:00:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 21:11:58



**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 23:00:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Oct 2020 21:11:58

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 23:00:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 21:11:58

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 23:00:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Oct 2020 21:11:58

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 23:00:38

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: LEVOCETIRIZINE DIHYDROCHLORIDE, PRODUCTSYNONYM: XYZAL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Nov 2020 18:53:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Nov 2020 18:53:16
Data point term sent to Coder	System	30 Nov 2020 18:51:45
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 18:51:43
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: LEVOCETIRIZINE DIHYDROCHLORIDE, PRODUCTSYNONYM: XYZAL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Nov 2020 16:46:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Nov 2020 16:46:44
Data point term sent to Coder	System	15 Nov 2020 16:46:01
Coding entries removed.	(b) (4), (b) (6)	15 Nov 2020 16:45:13
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: LEVOCETIRIZINE DIHYDROCHLORIDE, PRODUCTSYNONYM: XYZAL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 21:13:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 21:13:44
Data point term sent to Coder	System	29 Oct 2020 21:13:21
User entered 'Xyzal'	(b) (4), (b) (6)	29 Oct 2020 21:12:38

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 23:00:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 21:12:38

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 23:00:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered 'worsening of URITICARIA' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Nov 2020 16:45:13
User entered 'Urticaria'	(b) (4), (b) (6)	29 Oct 2020 21:12:38

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 23:00:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered '5'	(b) (4), (b) (6)	29 Oct 2020 21:12:38

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 23:00:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered 'mg (mg)'	(b) (4), (b) (6)	29 Oct 2020 21:12:38



US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 23:00:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:12:38

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 23:00:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered 'once daily (QD)'	(b) (4), (b) (6)	29 Oct 2020 21:12:38

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 23:00:38

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:12:38

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 23:00:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	29 Oct 2020 21:12:38

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 23:00:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:12:38

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 23:00:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered '19 Oct 2020'	(b) (4), (b) (6)	29 Oct 2020 21:12:38

US3672377

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 23:00:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered '0'	(b) (4), (b) (6)	29 Oct 2020 21:12:38

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 23:00:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 21:12:38



US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 23:00:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:12:38

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 23:00:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 18:51:43
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 21:12:38

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 23:00:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 21:12:38

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 23:00:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 21:12:38

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 23:00:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Oct 2020 21:12:38

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 23:00:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:38
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	08 Apr 2021 14:17:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 15:07:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Apr 2021 15:07:42
Data point term sent to Coder	System	05 Apr 2021 15:06:29
User entered 'hydrocodone/acetaminophen'	(b) (4), (b) (6)	05 Apr 2021 15:05:29

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 23:00:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:38
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:17:46
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 15:05:29

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 23:00:38**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:38
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:17:46
User entered 'pain secondary to tooth extraction'	(b) (4), (b) (6)	05 Apr 2021 15:05:29



**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 23:00:38**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:38
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:17:46
User entered '325/5'	(b) (4), (b) (6)	05 Apr 2021 15:05:29

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 23:00:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:38
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:17:46
User entered 'mg (mg)'	(b) (4), (b) (6)	05 Apr 2021 15:05:29

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 23:00:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:38
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	08 Apr 2021 14:17:46
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 15:05:29

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 23:00:38**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:38
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:17:46
User entered 'as needed (PRN)'	(b) (4), (b) (6)	05 Apr 2021 15:05:29

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 23:00:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:38
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:17:46
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 15:05:29

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 23:00:38**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:38
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:17:46
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Apr 2021 15:05:29

US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 23:00:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:38
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	08 Apr 2021 14:17:46
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 15:05:29

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 23:00:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:38
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	08 Apr 2021 14:17:46
User entered '16 Mar 2021'	(b) (4), (b) (6)	05 Apr 2021 15:05:29



US3672377

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 23:00:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:38
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	08 Apr 2021 14:17:46
User entered '0'	(b) (4), (b) (6)	05 Apr 2021 15:05:29

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 23:00:38**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:38
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 14:17:46
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 15:05:29

**US3672377**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 23:00:38**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:38
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	08 Apr 2021 14:17:46
User entered '17 Mar 2021'	(b) (4), (b) (6)	05 Apr 2021 15:05:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 23:00:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:38
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	08 Apr 2021 14:17:46
User entered 'No (N)'	(b) (4), (b) (6)	05 Apr 2021 15:05:29

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 23:00:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:38
User entered empty.	System	05 Apr 2021 15:05:29

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 23:00:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:38
User entered empty.	System	05 Apr 2021 15:05:29

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 23:00:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:55:38
User entered empty.	System	05 Apr 2021 15:05:29

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 23:00:38

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:06:38
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:55:48
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 15:03:25
User entered 'No (N)'	(b) (4), (b) (6)	22 Mar 2021 13:54:12



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 23:00:38

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:56:01
User entered '16 Mar 2021'	(b) (4), (b) (6)	05 Apr 2021 15:04:03

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**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 11 Aug 2021 23:00:38**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:56:01
User entered 'Tooth extraction'	(b) (4), (b) (6)	05 Apr 2021 15:04:03

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**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 11 Aug 2021 23:00:38**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 13:56:01
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	05 Apr 2021 15:04:03

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 23:00:38

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:49:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:56:01
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 15:04:03

**US3672377**

**Folder: End of Study (1)**

**Form: Dosing Discontinuation**

**Generated On: 11 Aug 2021 23:00:38**

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:27:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:56:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:29:50
User entered '30 Sep 2020'	(b) (4), (b) (6)	28 Oct 2020 16:11:17

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 23:00:38

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:27:11
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:56:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:29:50
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 18:18:40
Query 'Per CDM: Re- query: Per response, Please confirm and consider to update 'AE lines 5, 6, & 7' in specify filed instead of details .Thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 17:51:06
User opened query 'Per CDM: Re- query: Per response, Please confirm and consider to update 'AE lines 5, 6, & 7' in specify filed instead of details .Thank you. ' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 13:03:46
User closed query 'Per CDM; Please clarify specific AE referenced in specify field' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 04:15:02
Query 'Per CDM; Please clarify specific AE referenced in specify field' answered with 'AE lines 5, 6, & 7 ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 21:10:03
User opened query 'Per CDM; Please clarify specific AE referenced in specify field' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:41:57
User entered 'Physician decision (specify) (PHYSICIAN DECISION)'	(b) (4), (b) (6)	28 Oct 2020 16:11:17

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 23:00:38

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)	08 Apr 2021 13:56:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:29:50
User closed query 'Per CDM: Please, update the AE log line # reflecting the primary reason for dose discontinuation.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 12:45:21
Query 'Per CDM: Please, update the AE log line # reflecting the primary reason for dose discontinuation.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 18:18:46
User entered 'AE #5,6,7' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 18:18:40
User opened query 'Per CDM: Please, update the AE log line # reflecting the primary reason for dose discontinuation.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 17:59:17
User entered 'PHYSICIAN DECISION WITHDRAWAL OF EXPERIENCES AN AE OR SAW THAT, IN THE JUDGEMENT OF THE INVESTIGATOR, REQUIRES STUDY IP WITHDRAWAL DUE TO IT'S NATURE'	(b) (4), (b) (6)	28 Oct 2020 16:11:17