

US3672199 (Prod: Coastal Carolina Research Center)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:22:54

All time stamps listed in this document are displayed in GMT

US3672199

Form: Participant Creation

Data signed: (b) (4) 05 Mar 2021 18:00:34

Generated On: 10 Jun 2021 09:22:54

[Participant ID](#)

US3672199

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

US3672199

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 20:02:49

Generated On: 10 Jun 2021 09:22:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 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) 15 Feb 2021 20:02:48

Generated On: 10 Jun 2021 09:22:54

Date of Birth (MMM yyyy)	(b) (6) 1948
Age	71
Age Units	YEARS
Age (Derived)	71
Sex	Female <input type="radio"/> Male <input checked="" 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) 15 Feb 2021 20:02:48

Generated On: 10 Jun 2021 09:22:54

Date of Informed Consent (<i>dd MMM yyyy</i>)	19 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 20:02:48

Generated On: 10 Jun 2021 09:22:54

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 20:02:49

Generated On: 10 Jun 2021 09:22:54

Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 20:02:48

Generated On: 10 Jun 2021 09:22:54

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 20:02:48

Generated On: 10 Jun 2021 09:22:54

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 20:02:48

Generated On: 10 Jun 2021 09:22:54

Condition	PRE DIABETIES
Start date (dd MMM yyyy)	UN UNK 2010
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 NOV 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	NOV 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 20:02:48

Generated On: 10 Jun 2021 09:22:54

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 20:02:48

Generated On: 10 Jun 2021 09:22:54

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

US3672199

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 20:02:48

Generated On: 10 Jun 2021 09:22:54

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Feb 2021 20:02:48

Generated On: 10 Jun 2021 09:22:54

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 15 Feb 2021 20:02:48

Generated On: 10 Jun 2021 09:22:54

Condition	TYPE 2 DIABETES
Start date (dd MMM yyyy)	UN NOV 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 15 Feb 2021 20:02:48

Generated On: 10 Jun 2021 09:22:54

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

US3672199

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 15 Feb 2021 20:02:48

Generated On: 10 Jun 2021 09:22:54

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 15 Feb 2021 20:02:48

Generated On: 10 Jun 2021 09:22:54

Condition	BILATERAL CATARACTS
Start date (dd MMM yyyy)	
Start date completely unknown	True
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 APR 2019
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	APR 2019
Stop Year (derived)	2019

US3672199

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 20:02:49

Generated On: 10 Jun 2021 09:22:54

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 AUG 2020
Time of assessment (00:00-23:59)	14:01 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 14:01
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
BMI (xxx.x)	
BMI units	
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input 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) 15 Feb 2021 20:02:49

Generated On: 10 Jun 2021 09:22:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 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: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 20:02:49

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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 ☒

Specify

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) 15 Feb 2021 20:02:49

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	True
Specify	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) 15 Feb 2021 20:02:49

Generated On: 10 Jun 2021 09:22:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 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) 15 Feb 2021 20:02:49

Generated On: 10 Jun 2021 09:22:54

What was the date of randomization? (dd MMM yyyy) 19 AUG 2020

What was the participant's randomization number? 187020

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) 15 Feb 2021 20:02:49

Generated On: 10 Jun 2021 09:22:54

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) 15 Feb 2021 20:02:49

Generated On: 10 Jun 2021 09:22:54

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)	19 AUG 2020
Time of assessment (00:00-23:59)	14:01 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 14:01
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 20:02:49

Generated On: 10 Jun 2021 09:22:54

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)	19 AUG 2020
Time of assessment (00:00-23:59)	15:09 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 15:09
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 20:02:49

Generated On: 10 Jun 2021 09:22:54

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: Exposure

Data signed: (b) (4) 15 Feb 2021 20:02:49

Generated On: 10 Jun 2021 09:22:54

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) 19 AUG 2020

What was the treatment time? (00:00-23:59) 14:32 (24 HR)

Treatment Date and Time (derived) 19 AUG 2020 14:32

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) 15 Feb 2021 20:02:49

Generated On: 10 Jun 2021 09:22:54

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 AUG 2020

Collection time (00:00-23:59)

14:17 (24 HR)

Collection date and time (derived)

19 AUG 2020 14:17

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 20:02:49

Generated On: 10 Jun 2021 09:22:54

Collection date (dd MMM yyyy)			19 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:49	19 AUG 2020 13:49
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:02:49

Generated On: 10 Jun 2021 09:22:54

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: 10 Jun 2021 09:22:54

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.2 °F

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

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

PC Time Stamp 19 AUG 2020 15:16

PC Open Date & Time 19 AUG 2020 14:52

PC Close Date & Time 19 AUG 2020 17:22

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.4 °F

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

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

PC Time Stamp	20 AUG 2020 05:05
PC Open Date & Time	19 AUG 2020 18:17
PC Close Date & Time	20 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 07:36

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 07:00

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 06:00

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 06:12

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 08:19

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 07:55

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 16:45

PC Open Date & Time

19 AUG 2020 14:52

PC Close Date & Time

19 AUG 2020 17:22

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 05:06

PC Open Date & Time

19 AUG 2020 18:17

PC Close Date & Time

20 AUG 2020 11:59

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 07:37

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 07:00

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:54

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

23 AUG 2020 06:01

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 06:13

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 08:19

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 07:56

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

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 ☐

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

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

No ☒

Yes ☐

PC Time stamp	19 AUG 2020 16:46
PC Open Date & Time	19 AUG 2020 14:52
PC Close Date & Time	19 AUG 2020 17:22

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

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 ☐

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 05:07
PC Open Date & Time	19 AUG 2020 18:17
PC Close Date & Time	20 AUG 2020 11:59

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:54

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 ☒

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:54

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 07:38
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:54

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 ☒

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:54

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 07:01
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:54

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 ☒

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:54

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 06:01
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:54

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 ☒

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:54

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 06:13
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:54

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 08:20
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:54

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 ☒

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:54

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 07:56
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3672199

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:02:48

Generated On: 10 Jun 2021 09:22:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672199

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:02:48

Generated On: 10 Jun 2021 09:22:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672199

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:02:48

Generated On: 10 Jun 2021 09:22:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672199

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:02:48

Generated On: 10 Jun 2021 09:22:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672199

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:02:48

Generated On: 10 Jun 2021 09:22:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672199

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:02:48

Generated On: 10 Jun 2021 09:22:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672199

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 20:02:49

Generated On: 10 Jun 2021 09:22:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 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

US3672199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 20:02:49

Generated On: 10 Jun 2021 09:22:54

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)	18 SEP 2020
Time of assessment (00:00-23:59)	14:48 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 14:48
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3672199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 20:02:49

Generated On: 10 Jun 2021 09:22:54

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	18 SEP 2020
Time of assessment (00:00-23:59)	16:00 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 16:00
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3672199

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 20:02:49

Generated On: 10 Jun 2021 09:22:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 SEP 2020

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

US3672199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 20:02:49

Generated On: 10 Jun 2021 09:22:54

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) 18 SEP 2020

What was the treatment time? (00:00-23:59) 15:26 (24 HR)

Treatment Date and Time (derived) 18 SEP 2020 15:26

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

US3672199

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 20:02:49

Generated On: 10 Jun 2021 09:22:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 SEP 2020
Collection time (00:00-23:59)	15:02 (24 HR)
Collection date and time (derived)	18 SEP 2020 15:02

US3672199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 20:02:49

Generated On: 10 Jun 2021 09:22:54

Collection date (dd MMM yyyy)			18 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:55	18 SEP 2020 14:55
Nasopharyngeal Swab 2	No		

US3672199

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:02:49

Generated On: 10 Jun 2021 09:22:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 15:59

PC Open Date & Time

18 SEP 2020 15:46

PC Close Date & Time

18 SEP 2020 18:16

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.3 °F

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

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

PC Time Stamp	19 SEP 2020 07:46
PC Open Date & Time	18 SEP 2020 19:11
PC Close Date & Time	19 SEP 2020 11:59

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 SEP 2020 22:16

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 17:53

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 16:09

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 05:58

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 20:39

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 03:00

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 16:00

PC Open Date & Time

18 SEP 2020 15:46

PC Close Date & Time

18 SEP 2020 18:16

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 07:46

PC Open Date & Time

18 SEP 2020 19:11

PC Close Date & Time

19 SEP 2020 11:59

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 22:16

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 17:53

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:54

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

21 SEP 2020 16:10

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:54

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

23 SEP 2020 05:59

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:54

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

23 SEP 2020 20:39

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:54

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

25 SEP 2020 03:00

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

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 ☐

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

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

No ☒

Yes ☐

PC Time stamp	18 SEP 2020 16:00
PC Open Date & Time	18 SEP 2020 15:46
PC Close Date & Time	18 SEP 2020 18:16

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

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 ☐

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

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

No ☒

Yes ☐

PC Time stamp	19 SEP 2020 07:47
PC Open Date & Time	18 SEP 2020 19:11
PC Close Date & Time	19 SEP 2020 11:59

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:54

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 ☒

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:54

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 22:17
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

100 of 2365

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:54

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 17:54
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

102 of 2365

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:54

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 16:10
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:54

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 ☒

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:54

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 05:59
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:54

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 ☒

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:54

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 20:40
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:54

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 ☒

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:54

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 03:00
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3672199

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:02:48

Generated On: 10 Jun 2021 09:22:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672199

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:02:48

Generated On: 10 Jun 2021 09:22:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672199

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:02:48

Generated On: 10 Jun 2021 09:22:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672199

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:02:48

Generated On: 10 Jun 2021 09:22:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672199

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:02:48

Generated On: 10 Jun 2021 09:22:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672199

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:02:48

Generated On: 10 Jun 2021 09:22:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672199

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Apr 2021 14:31:34

Generated On: 10 Jun 2021 09:22:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 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

US3672199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 20:02:49

Generated On: 10 Jun 2021 09:22:54

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) _____

US3672199

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 20:02:49

Generated On: 10 Jun 2021 09:22:54

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.

US3672199

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 20:02:49

Generated On: 10 Jun 2021 09:22:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 OCT 2020
Collection time (00:00-23:59)	13:26 (24 HR)
Collection date and time (derived)	14 OCT 2020 13:26

US3672199

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:02:49

Generated On: 10 Jun 2021 09:22:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 OCT 2020 18:02:31

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59

US3672199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 OCT 2020 00:02:06

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3672199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 NOV 2020 12:00:55

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3672199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 12:00:55

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 00:02:47
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 NOV 2020 18:02:24

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

08 DEC 2020 13:59:03

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

13 DEC 2020 12:04:53

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 DEC 2020 12:01:04

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

Patient Cloud Open Date & Time	25 DEC 2020 00:01
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Patient Cloud Close Date & Time	29 DEC 2020 23:59
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US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	03 JAN 2021 12:10:34
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

08 JAN 2021 01:18:22

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 JAN 2021 20:34:04

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

22 JAN 2021 06:01:49

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 JAN 2021 07:36:38

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 FEB 2021 08:50:15

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

15 FEB 2021 18:07:44

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

19 FEB 2021 13:34:53

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

26 FEB 2021 02:28:26

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

05 MAR 2021 08:26:04

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

12 MAR 2021 12:19:03

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

19 MAR 2021 05:27:34

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

28 MAR 2021 12:55:36

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

02 APR 2021 08:25:22

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 03:42:49

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

18 APR 2021 13:33:46

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 18:12:47

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

Date and time of submission

02 MAY 2021 12:38:05

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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"/>

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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 ☐

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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"/>

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUN 2021 00:01
Patient Cloud Close Date & Time	15 JUN 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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"/>

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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 ☐

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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 ☐

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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"/>

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	16 JUL 2021 00:01
Patient Cloud Close Date & Time	20 JUL 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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"/>

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	13 AUG 2021 00:01
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Patient Cloud Close Date & Time	17 AUG 2021 23:59
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US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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 ☐

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

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 ☐

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	10 SEP 2021 00:01
Patient Cloud Close Date & Time	14 SEP 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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 ☐

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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"/>

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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"/>

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

Patient Cloud Open Date & Time	15 OCT 2021 00:01
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Patient Cloud Close Date & Time	19 OCT 2021 23:59
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US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	22 OCT 2021 00:01
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Patient Cloud Close Date & Time	26 OCT 2021 23:59
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US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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 ☐

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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"/>

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 467

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

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

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

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

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

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

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

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

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	26 NOV 2021 00:01
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Patient Cloud Close Date & Time	30 NOV 2021 23:59
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US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 474

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

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

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

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

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

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

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 ☐

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	10 DEC 2021 00:01
Patient Cloud Close Date & Time	14 DEC 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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"/>

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	17 DEC 2021 00:01
Patient Cloud Close Date & Time	21 DEC 2021 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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="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"/>

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2021 00:01
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Patient Cloud Close Date & Time	28 DEC 2021 23:59
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US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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 <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"/>

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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 ☐

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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"/>

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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°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 ☐

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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"/>

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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°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 ☐

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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="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"/>

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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 ☐

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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 ☐

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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 ☐

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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 ☐

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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 ☐

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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 ☐

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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"/>

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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"/>

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

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 ☐

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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 ☐

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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°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 ☐

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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 ☐

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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"/>

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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 ☐

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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 ☐

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

Patient Cloud Open Date & Time	15 JUL 2022 00:01
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Patient Cloud Close Date & Time	19 JUL 2022 23:59
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US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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 ☐

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

22 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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 ☐ 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 ☐

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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="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"/>

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	12 AUG 2022 00:01
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Patient Cloud Close Date & Time	16 AUG 2022 23:59
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US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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"/>

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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"/>

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	26 AUG 2022 00:01
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Patient Cloud Close Date & Time	30 AUG 2022 23:59
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US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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="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"/>

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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 ☐

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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"/>

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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"/>

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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 ☐

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

07 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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 ☐

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 OCT 2022 00:01
Patient Cloud Close Date & Time	18 OCT 2022 23:59

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3672199

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:22:54

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 08:20:35

US3672199

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:00:42

Generated On: 10 Jun 2021 09:22:54

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3672199

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:00:42

Generated On: 10 Jun 2021 09:22:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672199

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:00:42

Generated On: 10 Jun 2021 09:22:54

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 3 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3672199

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:00:42

Generated On: 10 Jun 2021 09:22:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672199

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:00:42

Generated On: 10 Jun 2021 09:22:54

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 _____

US3672199

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:00:42

Generated On: 10 Jun 2021 09:22:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672199

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:00:42

Generated On: 10 Jun 2021 09:22:54

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3672199

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:00:42

Generated On: 10 Jun 2021 09:22:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672199

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 15:10:39

Generated On: 10 Jun 2021 09:22:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3672199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 15:10:39

Generated On: 10 Jun 2021 09:22:54

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) _____

US3672199

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 15:10:39

Generated On: 10 Jun 2021 09:22:54

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.

US3672199

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 15:10:39

Generated On: 10 Jun 2021 09:22:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 MAR 2021
Collection time (00:00-23:59)	09:15 (24 HR)
Collection date and time (derived)	16 MAR 2021 09:15

US3672199

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 15:10:39

Generated On: 10 Jun 2021 09:22:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672199

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 15:10:39

Generated On: 10 Jun 2021 09:22:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672199

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 15:10:39

Generated On: 10 Jun 2021 09:22:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672199

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

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

US3672199

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:54

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3672199

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:22:54

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"/>

US3672199

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:22:54

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3672199

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

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 18:00:42

Generated On: 10 Jun 2021 09:22:54

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

Visit date (dd MMM yyyy)	19 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3672199

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 15:10:39

Generated On: 10 Jun 2021 09:22:54

Date of updated informed consent (<i>dd MMM yyyy</i>)	19 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	19 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3672199

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Mar 2021 18:00:42

Generated On: 10 Jun 2021 09:22:54

Height	
Weight	
BMI (xxx.x)	

US3672199

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 18:00:42

Generated On: 10 Jun 2021 09:22:54

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 JAN 2021
Time of assessment (00:00-23:59)	09:39 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 09:39
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3672199

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 18:00:42

Generated On: 10 Jun 2021 09:22:54

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 JAN 2021
Time of assessment (00:00-23:59)	10:35 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 10:35
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3672199

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

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 18:00:41

Generated On: 10 Jun 2021 09:22:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 JAN 2021

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

US3672199

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

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 18:00:41

Generated On: 10 Jun 2021 09:22:54

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 19 JAN 2021

What was the treatment time? (00:00-23:59) 10:04 (24 HR)

Treatment Date and Time (derived) 19 JAN 2021 10:04

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

US3672199

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 18:00:41

Generated On: 10 Jun 2021 09:22:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 JAN 2021
Collection time (00:00-23:59)	09:50 (24 HR)
Collection date and time (derived)	19 JAN 2021 09:50

US3672199

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Mar 2021 18:00:41

Generated On: 10 Jun 2021 09:22:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 JAN 2021
Collection time (00:00 - 23:59)	09:27
Collection Date and Time (derived)	19 JAN 2021 09:27

US3672199

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

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:00:41

Generated On: 10 Jun 2021 09:22:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672199

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:00:42

Generated On: 10 Jun 2021 09:22:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672199

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:00:42

Generated On: 10 Jun 2021 09:22:54

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

US3672199

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 18:00:41

Generated On: 10 Jun 2021 09:22:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3672199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 18:00:41

Generated On: 10 Jun 2021 09:22:54

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 (<i>dd MMM yyyy</i>)	16 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	08:48 (24 HR)
Vital Signs Date and Time (derived)	16 FEB 2021 08:48
Temperature (<i>xxx.x</i>)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	062 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	065 mmHg
Diastolic Blood Pressure units	MMHG

US3672199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 18:00:41

Generated On: 10 Jun 2021 09:22:54

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)	16 FEB 2021
Time of assessment (00:00-23:59)	09:22 (24 HR)
Vital Signs Date and Time (derived)	16 FEB 2021 09:22
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	056 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	060 mmHg
Diastolic Blood Pressure units	MMHG

US3672199

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 18:00:41

Generated On: 10 Jun 2021 09:22:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 FEB 2021

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

US3672199

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 18:00:41

Generated On: 10 Jun 2021 09:22:54

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 16 FEB 2021

What was the treatment time? (00:00-23:59) 08:51 (24 HR)

Treatment Date and Time (derived) 16 FEB 2021 08:51

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

US3672199

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:00:41

Generated On: 10 Jun 2021 09:22:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672199

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:00:42

Generated On: 10 Jun 2021 09:22:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3672199

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:00:42

Generated On: 10 Jun 2021 09:22:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672199

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 15:10:39

Generated On: 10 Jun 2021 09:22:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3672199

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 15:10:39

Generated On: 10 Jun 2021 09:22:54

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) _____

US3672199

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 15:10:39

Generated On: 10 Jun 2021 09:22:54

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.

US3672199

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 15:10:32

Generated On: 10 Jun 2021 09:22:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 MAR 2021
Collection time (00:00-23:59)	09:15 (24 HR)
Collection date and time (derived)	16 MAR 2021 09:15

US3672199

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 05 Mar 2021 18:00:35

Generated On: 10 Jun 2021 09:22:54

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3672199

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Apr 2021 20:44:03

Generated On: 10 Jun 2021 09:22:54

AEID	USA-US116-2020-MRNA-1273-P30 1000003
Adverse event	HEMATOMA R GROIN FOLLOWING ANGIOPLASTY
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)	6 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	8 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	6 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	8 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	349 of 2365

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Apr 2021 20:44:03

Generated On: 10 Jun 2021 09:22:54

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	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	

US3672199

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 12 Apr 2021 20:44:03

Generated On: 10 Jun 2021 09:22:54

SUBJECT HAD ANGIOPLASTY
SURGERY FOR MEDICAL
HISTORY OF PERIPHERAL
VASCULAR DISEASE. SUBJECT
WAS HOSPITALIZED FOR
HEMATOMA IN GROIN AREA
FOLLOWING ANGIOPLASTY.
SUBJECT HAD SURGERY ON 06
OCTOBER 2020 AND WAS
DISCHARGED 08 OCTOBER 2020.
SUBJECT PRESCRIBED
CIPROFLOXACIN AND
METRONIDAZOLE TO PREVENT
INFECTION.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 12 Apr 2021 20:44:03

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AEID

Adverse event

CARDIAC CHEST TIGHTNESS

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

20 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

22 AUG 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) 12 Apr 2021 20:44:03

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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	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 (3)

Data signed: (b) (4) 12 Apr 2021 20:44:03

Generated On: 10 Jun 2021 09:22:54

AEID	
Adverse event	SKIN ULCER RIGHT GREAT TOE
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)	01 DEC 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 (3)

Data signed: (b) (4) 12 Apr 2021 20:44:03

Generated On: 10 Jun 2021 09:22:54

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" 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 (4)

Data signed: (b) (4) 12 Apr 2021 20:44:03

Generated On: 10 Jun 2021 09:22:54

AEID	
Adverse event	SKIN ULCER LEFT HEEL
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)	01 DEC 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 (4)

Data signed: (b) (4) 12 Apr 2021 20:44:03

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Mar 2021 18:00:41

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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) 20 Apr 2021 15:32:48

Generated On: 10 Jun 2021 09:22:54

Name of Medication METOPROLOL TARTATE

Prophylaxis Yes ☐
No ☒

Indication HTN

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 (1)

Data signed: (b) (4) 20 Apr 2021 15:32:48

Generated On: 10 Jun 2021 09:22:54

	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 2010	
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) 20 Apr 2021 15:32:48

Generated On: 10 Jun 2021 09:22:54

Name of Medication TAMSULOSIN

Prophylaxis Yes ☐
No ☒

Indication BPH

Dose per administration 0.4

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) 20 Apr 2021 15:32:48

Generated On: 10 Jun 2021 09:22:54

	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 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 20 Apr 2021 15:32:48

Generated On: 10 Jun 2021 09:22:54

Name of Medication ATROVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HLD

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 (3)

Data signed: (b) (4) 20 Apr 2021 15:32:48

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	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 2010	
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 (4)

Data signed: (b) (4) 20 Apr 2021 15:32:48

Generated On: 10 Jun 2021 09:22:54

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIOVASCULAR DISEASE
PROPHYLAXIS

Dose per administration 81

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 (4)

Data signed: (b) (4) 20 Apr 2021 15:32:48

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	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2010
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 (5)

Data signed: (b) (4) 20 Apr 2021 15:32:48

Generated On: 10 Jun 2021 09:22:54

Name of Medication EZETIMIBE

Prophylaxis Yes ☐
No ☒

Indication HLD

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 (5)

Data signed: (b) (4) 20 Apr 2021 15:32:48

Generated On: 10 Jun 2021 09:22:54

	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 2010	
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 (6)

Data signed: (b) (4) 20 Apr 2021 15:32:48

Generated On: 10 Jun 2021 09:22:54

Name of Medication MELOXICAM

Prophylaxis Yes ☐
No ☒

Indication B/L TOE PAIN

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 20 Apr 2021 15:32:48

Generated On: 10 Jun 2021 09:22:54

	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 2010	
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 (7)

Data signed: (b) (4) 20 Apr 2021 15:32:48

Generated On: 10 Jun 2021 09:22:54

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication PREDIABESTES

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 (7)

Data signed: (b) (4) 20 Apr 2021 15:32:48

Generated On: 10 Jun 2021 09:22:54

	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 2010	
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 (8)

Data signed: (b) (4) 20 Apr 2021 15:32:48

Generated On: 10 Jun 2021 09:22:54

Name of Medication CIPROFLOXACIN

Prophylaxis Yes ☒
No ☐

Indication INFECTION PROPHYLAXIS

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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EAB) (1725)

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 20 Apr 2021 15:32:48

Generated On: 10 Jun 2021 09:22:54

	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)	8 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)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 20 Apr 2021 15:32:48

Generated On: 10 Jun 2021 09:22:54

Name of Medication METRONIDAZOLE

Prophylaxis Yes ☒
No ☐

Indication INFECTION PROPHYLAXIS

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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EAB) (1725)

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US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 20 Apr 2021 15:32:48

Generated On: 10 Jun 2021 09:22:54

	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)	8 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"/>

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 20 Apr 2021 15:32:48

Generated On: 10 Jun 2021 09:22:54

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 20 Apr 2021 15:32:48

Generated On: 10 Jun 2021 09:22:54

	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 2010	
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"/>

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 20 Apr 2021 15:32:48

Generated On: 10 Jun 2021 09:22:54

Name of Medication ZOSYN

Prophylaxis Yes ☒
No ☐

Indication POST ANGIOPLASTY
INFECTION PREVENTION

Dose per administration UNK

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 20 Apr 2021 15:32:48

Generated On: 10 Jun 2021 09:22:54

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

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 20 Apr 2021 15:32:48

Generated On: 10 Jun 2021 09:22:54

Name of Medication LACTATE

Prophylaxis Yes ☒
No ☐

Indication POST ANGIOPLASTY
INFECTION PREVENTION

Dose per administration UNK

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 20 Apr 2021 15:32:48

Generated On: 10 Jun 2021 09:22:54

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

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 20 Apr 2021 15:32:48

Generated On: 10 Jun 2021 09:22:54

Name of Medication TAMSULOSIN

Prophylaxis Yes ☐
No ☒

Indication BPH

Dose per administration .4

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 (13)

Data signed: (b) (4) 20 Apr 2021 15:32:48

Generated On: 10 Jun 2021 09:22:54

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		02 SEP 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"/>

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 20 Apr 2021 15:32:48

Generated On: 10 Jun 2021 09:22:54

Name of Medication AMOXICILLIN

Prophylaxis Yes ☐
No ☒

Indication SKIN ULCER RIGHT GREAT TOE

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 20 Apr 2021 15:32:48

Generated On: 10 Jun 2021 09:22:54

	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)	03 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)	10 MAR 2021	
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"/>

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 20 Apr 2021 15:32:48

Generated On: 10 Jun 2021 09:22:54

Name of Medication BACTRIM

Prophylaxis Yes ☐
No ☒

Indication SKIN ULCER LEFT HEEL

Dose per administration 160

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 20 Apr 2021 15:32:48

Generated On: 10 Jun 2021 09:22:54

	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 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"/>

US3672199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Mar 2021 18:00:41

Generated On: 10 Jun 2021 09:22:54

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3672199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 05 Mar 2021 18:00:41

Generated On: 10 Jun 2021 09:22:54

Procedure/Surgery date (<i>dd MMM</i> <i>yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
6 OCT 2020	ANGIOPLASTY SURGERY	Medical History	

US3672199

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:22:54

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3672199

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:22:54

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 ☐

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 05 Mar 2021 18:00:42

Generated On: 10 Jun 2021 09:22:54

SAEID	USA-US116-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CYNTHIA
Investigator's Last Name	STROUT
Site Address: Street	1156 BOWMAN ROAD
Site Address: City	MOUNT PLEASANT
Site Address: State	
Site Address: Postal Code	29464
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 05 Mar 2021 18:00:42

Generated On: 10 Jun 2021 09:22:54

SAEID	USA-US116-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CYNTHIA
Investigator's Last Name	STROUT
Site Address: Street	1156 BOWMAN ROAD
Site Address: City	MOUNT PLEASANT
Site Address: State	
Site Address: Postal Code	29464
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	13/OCT/2020 13:49
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 05 Mar 2021 18:00:42

Generated On: 10 Jun 2021 09:22:54

SAEID	USA-US116-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CYNTHIA
Investigator's Last Name	STROUT
Site Address: Street	1156 BOWMAN ROAD
Site Address: City	MOUNT PLEASANT
Site Address: State	
Site Address: Postal Code	29464
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	29/OCT/2020 11:11
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 05 Mar 2021 18:00:42

Generated On: 10 Jun 2021 09:22:54

SAEID	USA-US116-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CYNTHIA
Investigator's Last Name	STROUT
Site Address: Street	1156 BOWMAN ROAD
Site Address: City	MOUNT PLEASANT
Site Address: State	
Site Address: Postal Code	29464
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	02/NOV/2020 16:22
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 05 Mar 2021 18:00:42

Generated On: 10 Jun 2021 09:22:54

SAEID	USA-US116-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CYNTHIA
Investigator's Last Name	STROUT
Site Address: Street	1156 BOWMAN ROAD
Site Address: City	MOUNT PLEASANT
Site Address: State	
Site Address: Postal Code	29464
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	18/DEC/2020 15:30
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Data signed: (b) (4) 05 Mar 2021 18:00:42

Generated On: 10 Jun 2021 09:22:54

SAEID	USA-US116-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CYNTHIA
Investigator's Last Name	STROUT
Site Address: Street	1156 BOWMAN ROAD
Site Address: City	MOUNT PLEASANT
Site Address: State	
Site Address: Postal Code	29464
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	12/JAN/2021 16:29
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3672199 (Prod: Coastal Carolina Research Center)

US3672199

Form: Participant Creation

Generated On: 10 Jun 2021 09:22:54

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'US3672199'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 18:04:20

US3672199

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:22:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4) Patty Howenstine (b) (4)	19 Aug 2020 18:42:00

US3672199

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '19 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 18:04:21

US3672199

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Clinic (Clinic)'	(b) (4) Patty Howenstine (b) (4)	19 Aug 2020 18:42:00

US3672199

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:22:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered 'SCRN'	System	19 Aug 2020 18:42:00

US3672199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered (b) (6) 1948'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 18:04:23

US3672199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:54

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User closed query 'Age does not fit Date of Birth.' (Site from System).	(b) (4) System	21 Oct 2020 18:09:52
User entered '71' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 18:09:52
User opened query 'Age does not fit Date of Birth.' (Site from System).	System	19 Aug 2020 18:42:18
User entered '72'	Patty Howenstine (b) (4)	19 Aug 2020 18:42:09
	(b) (4)	

US3672199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:54

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered 'YEARS'	System	19 Aug 2020 18:42:09

US3672199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:54

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered '71'	System	19 Aug 2020 18:42:18

US3672199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:54

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Male (M)'	(b) (4) Patty Howenstine (b) (4)	19 Aug 2020 18:42:09

US3672199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:54

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Patty Howenstine (b) (4)	19 Aug 2020 18:42:09

US3672199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:54

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'I'	(b) (4) Patty Howenstine (b) (4)	19 Aug 2020 18:42:09

US3672199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:54

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '0'	(b) (4) Patty Howenstine (b) (4)	19 Aug 2020 18:42:09

US3672199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:54

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '0'	(b) (4) Patty Howenstine (b) (4)	19 Aug 2020 18:42:09

US3672199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:54

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '0'	(b) (4) Patty Howenstine (b) (4)	19 Aug 2020 18:42:09

US3672199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:54

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '0'	(b) (4) Patty Howenstine (b) (4)	19 Aug 2020 18:42:09

US3672199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:54

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '0'	(b) (4) Patty Howenstine (b) (4)	19 Aug 2020 18:42:09

US3672199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:54

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty.	(b) (4) Patty Howenstine (b) (4)	19 Aug 2020 18:42:09

US3672199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:54

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '0'	(b) (4) Patty Howenstine (b) (4)	19 Aug 2020 18:42:09

US3672199

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:22:54

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '0'	(b) (4) Patty Howenstine (b) (4)	19 Aug 2020 18:42:09

US3672199

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:22:54

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '19 Aug 2020'	(b) (4) Patty Howenstine (b) (4)	19 Aug 2020 18:42:18

US3672199

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered 'Aug 2020'	System	19 Aug 2020 18:42:18

US3672199

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered '2020'	System	19 Aug 2020 18:42:18

US3672199

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:22:54

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Amendment 2 (2)'	(b) (4) Patty Howenstine (b) (4)	19 Aug 2020 18:42:18

US3672199

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4) Patty Howenstine (b) (4)	19 Aug 2020 18:42:18

US3672199

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty.	(b) (4) Patty Howenstine (b) (4)	19 Aug 2020 18:42:18

US3672199

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:22:54

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty.	(b) (4) Patty Howenstine (b) (4)	19 Aug 2020 18:42:18

US3672199

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:22:54

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'No (N)'	(b) (4) Patty Howenstine (b) (4)	19 Aug 2020 18:42:18

US3672199

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:22:54

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 18:04:21

US3672199

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:22:54

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered 'I'	System	19 Aug 2020 18:42:21

US3672199

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:22:54

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4) Patty Howenstine (b) (4)	19 Aug 2020 18:42:21

US3672199

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:22:54

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:27:30

US3672199

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:22:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 13:29:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 13:29:12
Data point term sent to Coder	System	21 Aug 2020 13:28:16
User entered 'HYPERLIPIDEMIA'	(b) (4), (b) (6)	21 Aug 2020 13:27:55

US3672199

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'UN UNK 2010'	(b) (4), (b) (6)	21 Aug 2020 13:27:55

US3672199

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:22:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:27:55

US3672199

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:22:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 13:27:55

US3672199

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:22:54

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:27:55

US3672199

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:22:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:27:55

US3672199

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:22:54

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered 'Jan 2010'	System	21 Aug 2020 13:27:55

US3672199

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:22:54

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered '2010'	System	21 Aug 2020 13:27:55

US3672199

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:22:54

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered empty.	System	21 Aug 2020 13:27:55

US3672199

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:22:54

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered empty.	System	21 Aug 2020 13:27:55

US3672199

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:22:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 13:30:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 13:30:17
Data point term sent to Coder	System	21 Aug 2020 13:29:18
User entered 'HYPERTENSION'	(b) (4), (b) (6)	21 Aug 2020 13:28:20

US3672199

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:28:20

US3672199

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:22:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:28:20

US3672199

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:22:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 13:28:20

US3672199

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:22:54

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:28:20

US3672199

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:22:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:28:20

US3672199

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:22:54

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered 'Jan 2010'	System	21 Aug 2020 13:28:20

US3672199

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:22:54

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered '2010'	System	21 Aug 2020 13:28:20

US3672199

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:22:54

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered empty.	System	21 Aug 2020 13:28:20

US3672199

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:22:54

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered empty.	System	21 Aug 2020 13:28:20

US3672199

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:22:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Glucose tolerance impaired, LLT: Pre-diabetes - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 08:59:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 08:59:12
Data point term sent to Coder	System	21 Aug 2020 13:29:18
User entered 'PRE DIABETIES'	(b) (4), (b) (6)	21 Aug 2020 13:28:47

US3672199

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:28:47

US3672199

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:22:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:28:47

US3672199

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:22:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 13:41:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 13:28:47

US3672199

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:22:54

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'un Nov 2016' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 13:41:19
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:28:47

US3672199

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:22:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:28:47

US3672199

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:22:54

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered 'Jan 2010'	System	21 Aug 2020 13:28:47

US3672199

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:22:54

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered '2010'	System	21 Aug 2020 13:28:47

US3672199

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:22:54

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered 'Nov 2016'	System	05 Nov 2020 13:41:19
User entered empty.	System	21 Aug 2020 13:28:47

US3672199

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:22:54

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered '2016'	System	05 Nov 2020 13:41:19
User entered empty.	System	21 Aug 2020 13:28:47

US3672199

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:22:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User coded data point as SOC: Reproductive system and breast disorders, HLG: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: BPH - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 13:30:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 13:30:15
Data point term sent to Coder	System	21 Aug 2020 13:29:21
User entered 'BPH'	(b) (4), (b) (6)	21 Aug 2020 13:29:16

US3672199

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:29:16

US3672199

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:22:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:29:16

US3672199

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:22:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:29:16

US3672199

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:22:54

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:29:16

US3672199

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:22:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:29:16

US3672199

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:22:54

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered 'Jan 2010'	System	21 Aug 2020 13:29:16

US3672199

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:22:54

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered '2010'	System	21 Aug 2020 13:29:16

US3672199

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:22:54

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered empty.	System	21 Aug 2020 13:29:16

US3672199

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:22:54

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered empty.	System	21 Aug 2020 13:29:16

US3672199

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:22:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Pain in extremity, LLT: Pain in toe - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 21:22:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 21:22:19
Data point term sent to Coder	System	21 Aug 2020 13:30:22
User entered 'B/L TOE PAIN'	(b) (4), (b) (6)	21 Aug 2020 13:29:48

US3672199

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'UN UNK 2010'	(b) (4), (b) (6)	21 Aug 2020 13:29:48

US3672199

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:22:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:29:48

US3672199

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:22:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 13:29:48

US3672199

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:22:54

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:29:48

US3672199

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:22:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:29:48

US3672199

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:22:54

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered 'Jan 2010'	System	21 Aug 2020 13:29:48

US3672199

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:22:54

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered '2010'	System	21 Aug 2020 13:29:48

US3672199

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:22:54

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered empty.	System	21 Aug 2020 13:29:48

US3672199

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:22:54

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered empty.	System	21 Aug 2020 13:29:48

US3672199

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:22:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User closed query 'Per DM CLR: Please update the condition to include the type and/or location of Gout (i.e. bilateral, left, right - big toe, ankles, knees, elbows, wrists, fingers, etc). 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 17:12:45
Query 'Per DM CLR: Please update the condition to include the type and/or location of Gout (i.e. bilateral, left, right - big toe, ankles, knees, elbows, wrists, fingers, etc). 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 'THIS IS AN INAPPROPRIATE REQUEST AS THIS CAN MOVE TO OTHER JOINTS AND THAT WOULD NOT REQUIRE A WORSENING OF THE CONDITION TO DO SO' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 21:01:57
User opened query 'Per DM CLR: Please update the condition to include the type and/or location of Gout (i.e. bilateral, left, right - big toe, ankles, knees, elbows, wrists, fingers, etc). 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)	22 Oct 2020 17:55:51
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\23.0.	Coder Import (b) (4)	21 Aug 2020 13:32:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Aug 2020 13:32:19
Data point term sent to Coder	System	21 Aug 2020 13:31:28
User entered 'GOUT'	(b) (4), (b) (6)	21 Aug 2020 13:31:23

US3672199

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:31:23

US3672199

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:22:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:31:23

US3672199

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:22:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:31:23

US3672199

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:22:54

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:31:23

US3672199

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:22:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:31:23

US3672199

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:22:54

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered 'Jan 2010'	System	21 Aug 2020 13:31:23

US3672199

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:22:54

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered '2010'	System	21 Aug 2020 13:31:23

US3672199

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:22:54

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered empty.	System	21 Aug 2020 13:31:23

US3672199

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:22:54

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered empty.	System	21 Aug 2020 13:31:23

US3672199

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:22:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User coded data point as SOC: Vascular disorders, HLT: Vascular disorders NEC, HLT: Peripheral vascular disorders NEC, PT: Peripheral vascular disorder, LLT: Peripheral vascular disease - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 17:51:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 17:51:55
Data point term sent to Coder	System	30 Oct 2020 17:51:07
User entered 'peripheral vascular disease'	(b) (4), (b) (6)	30 Oct 2020 17:51:04

US3672199

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:51:04

US3672199

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:22:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 17:51:04

US3672199

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:22:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:51:04

US3672199

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:22:54

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:51:04

US3672199

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:22:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 17:51:04

US3672199

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:22:54

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered 'Jan 2010'	System	30 Oct 2020 17:51:04

US3672199

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:22:54

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered '2010'	System	30 Oct 2020 17:51:04

US3672199

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:22:54

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered empty.	System	30 Oct 2020 17:51:04

US3672199

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:22:54

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered empty.	System	30 Oct 2020 17:51:04

US3672199

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:22:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 13:43:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 13:43:18
Data point term sent to Coder	System	05 Nov 2020 13:42:10
User entered 'type 2 diabetes'	(b) (4), (b) (6)	05 Nov 2020 13:41:42

US3672199

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'un Nov 2016'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 13:41:42

US3672199

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:22:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 13:41:42

US3672199

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:22:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 13:41:42

US3672199

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:22:54

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 13:41:42

US3672199

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:22:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 13:41:42

US3672199

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:22:54

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered 'Nov 2016'	System	05 Nov 2020 13:41:42

US3672199

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:22:54

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered '2016'	System	05 Nov 2020 13:41:42

US3672199

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:22:54

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered empty.	System	05 Nov 2020 13:41:42

US3672199

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:22:54

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered empty.	System	05 Nov 2020 13:41:42

US3672199

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:22:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 13:43:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 13:43:18
Data point term sent to Coder	System	05 Nov 2020 13:42:10
User entered 'obesity'	(b) (4), (b) (6)	05 Nov 2020 13:41:59

US3672199

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 13:41:59

US3672199

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:22:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 13:41:59

US3672199

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:22:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 13:41:59

US3672199

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:22:54

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 13:41:59

US3672199

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:22:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 13:41:59

US3672199

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:22:54

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered 'Jan 2010'	System	05 Nov 2020 13:41:59

US3672199

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:22:54

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered '2010'	System	05 Nov 2020 13:41:59

US3672199

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:22:54

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered empty.	System	05 Nov 2020 13:41:59

US3672199

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:22:54

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered empty.	System	05 Nov 2020 13:41:59

US3672199

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:22:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User coded data point as SOC: Reproductive system and breast disorders, HLG: Sexual function and fertility disorders, HLT: Erection and ejaculation conditions and disorders, PT: Erectile dysfunction, LLT: Erectile dysfunction - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 13:44:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 13:44:18
Data point term sent to Coder	System	05 Nov 2020 13:43:13
User entered 'erectile dysfunction'	(b) (4), (b) (6)	05 Nov 2020 13:42:18

US3672199

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 13:42:18

US3672199

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:22:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 13:42:18

US3672199

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:22:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 13:42:18

US3672199

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:22:54

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 13:42:18

US3672199

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:22:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 13:42:18

US3672199

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:22:54

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered 'Jan 2010'	System	05 Nov 2020 13:42:18

US3672199

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:22:54

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered '2010'	System	05 Nov 2020 13:42:18

US3672199

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:22:54

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered empty.	System	05 Nov 2020 13:42:18

US3672199

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:22:54

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered empty.	System	05 Nov 2020 13:42:18

US3672199

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:22:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Bilateral cataracts - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 13:44:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 13:44:18
Data point term sent to Coder	System	05 Nov 2020 13:43:11
User entered 'bilateral cataracts'	(b) (4), (b) (6)	05 Nov 2020 13:42:37

US3672199

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 13:42:37

US3672199

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:22:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'I'	(b) (4), (b) (6)	05 Nov 2020 13:42:37

US3672199

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:22:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Nov 2020 13:44:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 13:44:11
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 13:44:11
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 13:42:37
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 13:42:37

US3672199

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:22:54

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'un Apr 2019'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 13:42:37

US3672199

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:22:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 13:42:37

US3672199

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:22:54

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered empty.	System	05 Nov 2020 13:42:37

US3672199

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:22:54

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered empty.	System	05 Nov 2020 13:42:37

US3672199

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:22:54

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered 'Apr 2019'	System	05 Nov 2020 13:42:37

US3672199

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:22:54

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered '2019'	System	05 Nov 2020 13:42:37

US3672199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 13:35:04

US3672199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '19 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 13:35:04

US3672199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '14:01'	(b) (4), (b) (6)	21 Aug 2020 13:35:04

US3672199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered '19 Aug 2020 14:01'	System	21 Aug 2020 13:35:04

US3672199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User closed query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, HEIGHT and WEIGHT should be recorded for Screenig Visit. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:59:20
Query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, HEIGHT and WEIGHT should be recorded for Screenig Visit. Please update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 15:24:14
User opened query 'Per CDM: It has been noted that Screening and Visit Day1 have been done on the same day. Per CCGs pages 15-16, If a participant is screened, enrolled, randomized, and dose on the same day, HEIGHT and WEIGHT should be recorded for Screenig Visit. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 15:14:05
User entered missing code ND - Not Done.	(b) (4), (b) (6)	21 Aug 2020 13:35:04
DataPoint set to visible.	System	19 Aug 2020 18:42:21

US3672199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:35:04
DataPoint set to visible.	System	19 Aug 2020 18:42:21

US3672199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered empty.	System	21 Aug 2020 13:35:04
DataPoint set to visible.	System	19 Aug 2020 18:42:21

US3672199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered empty.	System	21 Aug 2020 13:35:04
DataPoint set to visible.	System	19 Aug 2020 18:42:21

US3672199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered missing code ND - Not Done.	(b) (4), (b) (6)	21 Aug 2020 13:35:04

US3672199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 15:24:09
User entered 'Other (Other)'	(b) (4), (b) (6)	21 Aug 2020 13:35:04

US3672199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered missing code ND - Not Done.	(b) (4), (b) (6)	21 Aug 2020 13:35:04

US3672199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered missing code ND - Not Done.	(b) (4), (b) (6)	21 Aug 2020 13:35:04

US3672199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered 'bpm'	System	21 Aug 2020 13:35:04

US3672199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered missing code ND - Not Done.	(b) (4), (b) (6)	21 Aug 2020 13:35:04

US3672199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered 'breaths/min'	System	21 Aug 2020 13:35:04

US3672199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered missing code ND - Not Done.	(b) (4), (b) (6)	21 Aug 2020 13:35:04

US3672199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered 'mmHg'	System	21 Aug 2020 13:35:04

US3672199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:35:04

US3672199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User entered 'mmHg'	System	21 Aug 2020 13:35:04

US3672199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45

US3672199

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45

US3672199

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:35:20

US3672199

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:35:20

US3672199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:54

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:48:57

US3672199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:54

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 13:48:57

US3672199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:54

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)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 13:48:57

US3672199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:54

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)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 13:48:57

US3672199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:54

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 13:48:57

US3672199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:54

[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)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 13:48:57

US3672199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:54

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)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 13:48:57

US3672199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:54

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)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 13:48:57

US3672199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:54

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)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:48:57

US3672199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:54

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)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 13:48:57

US3672199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:54

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)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 13:48:57

US3672199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:54

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 13:48:57

US3672199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:54

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:48:57

US3672199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:54

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:48:57

US3672199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:54

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:48:57

US3672199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:54

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)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:48:57

US3672199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:54

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)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:48:57

US3672199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:54

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)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:48:57

US3672199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:54

Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'I'	(b) (4), (b) (6)	21 Aug 2020 13:48:57

US3672199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:54

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'I'	(b) (4), (b) (6)	21 Aug 2020 13:48:57

US3672199

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:22:54

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:47:45
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'RESIDENT IN A COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION.'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:48:57

US3672199

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:22:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4) Patty Howenstine (b) (4)	19 Aug 2020 18:42:32

US3672199

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '19 Aug 2020'	(b) (4) Patty Howenstine (b) (4)	19 Aug 2020 18:42:32

US3672199

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Clinic (Clinic)'	(b) (4) Patty Howenstine (b) (4)	19 Aug 2020 18:42:32

US3672199

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:22:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered 'VISIT1'	System	19 Aug 2020 18:42:32

US3672199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:02:29
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:02:22
User entered '19 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 18:14:16

US3672199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:22:54

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:02:31
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:02:22
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 05:38:54
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:38:54
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Aug 2020 18:14:16
User entered '187020' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 18:14:16

US3672199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:22:54

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:02:32
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:02:22
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 18:14:16

US3672199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:22:54

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:02:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:02:22
User entered 'No (N)'	Patty Howenstine (b) (4)	19 Aug 2020 18:42:42
	(b) (4)	

US3672199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:22:54

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
DataPoint Un-verified.	(b) (4)	05 Nov 2020 20:02:37
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:02:22
User closed query 'Per source, this should be changed to Yes as subject suffers from HTN. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 20:02:14
Query 'Per source, this should be changed to Yes as subject suffers from HTN. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 19:32:02
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 19:31:55
User opened query 'Per source, this should be changed to Yes as subject suffers from HTN. ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 14:40:29
User entered 'No (N)'	Patty Howenstine (b) (4)	19 Aug 2020 18:42:42

US3672199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:22:54

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:02:39
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:02:22
User entered 'No (N)'	Patty Howenstine (b) (4)	19 Aug 2020 18:42:42
	(b) (4)	

US3672199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:22:54

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:02:40
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:02:22
User closed query 'Per source, this should be Yes as subject suffers from T2DM.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 20:02:17
Query 'Per source, this should be Yes as subject suffers from T2DM.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 19:32:04
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 19:31:55
User opened query 'Per source, this should be Yes as subject suffers from T2DM.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 14:40:59
User entered 'No (N)'	Patty Howenstine (b) (4)	19 Aug 2020 18:42:42
	(b) (4)	

US3672199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:22:54

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:02:42
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:02:22
User entered 'No (N)'	Patty Howenstine (b) (4)	19 Aug 2020 18:42:42
	(b) (4)	

US3672199

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:22:54

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:02:43
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 20:02:22
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 19:31:55
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:36:03
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:34:41

US3672199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:54

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:50:42

US3672199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:54

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered missing code ND - Not Done.	(b) (4), (b) (6)	21 Aug 2020 13:50:42

US3672199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:54

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered missing code ND - Not Done.	(b) (4), (b) (6)	21 Aug 2020 13:50:42

US3672199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:54

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered missing code ND - Not Done.	(b) (4), (b) (6)	21 Aug 2020 13:50:42

US3672199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	21 Aug 2020 13:50:42

US3672199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:50:42

US3672199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '19 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 13:50:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '14:01'	(b) (4), (b) (6)	21 Aug 2020 13:50:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered '19 Aug 2020 14:01'	System	21 Aug 2020 13:50:42

US3672199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 13:51:40
User entered '98.1' F reason for change: Data Entry Error	System	21 Aug 2020 13:51:40
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	21 Aug 2020 13:50:42
User entered '98' (non-conformant).	System	21 Aug 2020 13:50:42
	(b) (4), (b) (6)	21 Aug 2020 13:50:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 13:51:48
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Aug 2020 13:51:48
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 13:51:48
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 13:51:40
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:50:42

US3672199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:50:42

US3672199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 13:51:40
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Aug 2020 13:51:40
User entered '78' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 13:51:40
User opened query 'Data is required. Please provide.' (Site from System).		21 Aug 2020 13:50:42
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:50:42

US3672199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered 'bpm'	System	21 Aug 2020 13:51:40
User entered empty.	System	21 Aug 2020 13:50:42

US3672199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 13:51:40
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Aug 2020 13:51:40
User entered '15' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 13:51:40
User opened query 'Data is required. Please provide.' (Site from System).		21 Aug 2020 13:50:42
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:50:42

US3672199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered 'breaths/min'	System	21 Aug 2020 13:51:40
User entered empty.	System	21 Aug 2020 13:50:42

US3672199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 13:51:40
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Aug 2020 13:51:40
User entered '137' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 13:51:40
User opened query 'Data is required. Please provide.' (Site from System).		21 Aug 2020 13:50:42
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:50:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered 'mmHg'	System	21 Aug 2020 13:51:40
User entered empty.	System	21 Aug 2020 13:50:42

US3672199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 13:51:40
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Aug 2020 13:51:40
User entered '71' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 13:51:40
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 13:50:42
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:50:42

US3672199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered 'mmHg'	System	21 Aug 2020 13:51:40
User entered empty.	System	21 Aug 2020 13:50:42

US3672199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:54

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered missing code ND - Not Done.	(b) (4), (b) (6)	21 Aug 2020 13:50:42

US3672199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:54

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered missing code ND - Not Done.	(b) (4), (b) (6)	21 Aug 2020 13:50:42

US3672199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	21 Aug 2020 13:50:42

US3672199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:50:42

US3672199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 13:52:53
User entered '19 Aug 2020' reason for change: Data Entry Error	System	21 Aug 2020 13:52:53
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	21 Aug 2020 13:50:42
User entered empty.	(b) (4)	21 Aug 2020 13:50:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 13:52:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Aug 2020 13:52:53
User entered '15:09' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 13:52:53
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 13:50:42
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:50:42

US3672199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered '19 Aug 2020 15:09'	System	21 Aug 2020 13:52:53
User entered empty.	System	21 Aug 2020 13:50:42

US3672199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 13:52:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Aug 2020 13:52:53
User entered '97.2' F reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 13:52:53
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 13:50:42
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:50:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 13:52:59
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Aug 2020 13:52:59
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 13:52:59
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 13:52:53
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:50:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:50:42

US3672199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 13:52:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Aug 2020 13:52:53
User entered '80' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 13:52:53
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 13:50:42
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:50:42

US3672199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered 'bpm'	System	21 Aug 2020 13:52:53
User entered empty.	System	21 Aug 2020 13:50:42

US3672199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 13:52:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Aug 2020 13:52:53
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 13:52:53
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 13:50:42
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:50:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered 'breaths/min'	System	21 Aug 2020 13:52:53
User entered empty.	System	21 Aug 2020 13:50:42

US3672199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 13:52:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Aug 2020 13:52:53
User entered '140' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 13:52:53
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 13:50:42
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:50:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered 'mmHg'	System	21 Aug 2020 13:52:53
User entered empty.	System	21 Aug 2020 13:50:42

US3672199

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	21 Aug 2020 13:52:53
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	21 Aug 2020 13:52:53
User entered '78' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 13:52:53
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 13:50:42
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:50:42

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered 'mmHg'	System	21 Aug 2020 13:52:53
User entered empty.	System	21 Aug 2020 13:50:42

US3672199

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:53:15

US3672199

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:53:15

US3672199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:22:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:03:13

US3672199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:22:54

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:03:13

US3672199

Folder: Visit 1 Day 1

Form: Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:03:13

US3672199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:22:54

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered 'MRNA-1273 OR PLACEBO'	System	19 Aug 2020 19:03:13

US3672199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:22:54

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:03:13

US3672199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:22:54

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '14:32'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:03:13

US3672199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:22:54

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered '19 Aug 2020 14:32'	System	19 Aug 2020 19:03:13

US3672199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:22:54

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 19:03:13

US3672199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:22:54

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered 'ONCE'	System	19 Aug 2020 19:03:13

US3672199

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:22:54

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered 'INTRAMUSCULAR'	System	19 Aug 2020 19:03:13

US3672199

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 13:56:23

US3672199

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '19 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 13:56:23

US3672199

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:54

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '14:17'	(b) (4), (b) (6)	21 Aug 2020 13:56:23

US3672199

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered '19 Aug 2020 14:17'	System	21 Aug 2020 13:56:23

US3672199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:22:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '19 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 13:56:47

US3672199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:22:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	21 Aug 2020 13:56:47

US3672199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:22:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:56:47

US3672199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:22:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '13:49'	(b) (4), (b) (6)	21 Aug 2020 13:56:47

US3672199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:22:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered '19 Aug 2020 13:49'	System	21 Aug 2020 13:56:47

US3672199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:22:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	21 Aug 2020 13:56:47

US3672199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:22:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:56:47

US3672199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:22:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:56:47

US3672199

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:22:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered empty.	System	21 Aug 2020 13:56:47

US3672199

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:22:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 13:56:54

US3672199

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:22:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered 'I'	System	21 Aug 2020 13:56:54

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	19 Aug 2020 19:03:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-19T15:15:45', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '8abe81ab-3cd7-408c-9d6d-e2711211027c' User entered 'Yes (Y)'	System	19 Aug 2020 19:16:11
	System	19 Aug 2020 19:16:11

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-19T15:15:55', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '8abe81ab-3cd7-408c-9d6d-e2711211027c' User entered '97.2'	System	19 Aug 2020 19:16:11
	System	19 Aug 2020 19:16:11

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-19T15:16:04', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '8abe81ab-3cd7-408c-9d6d-e2711211027c'	System	19 Aug 2020 19:16:11
User entered 'No (N)'	System	19 Aug 2020 19:16:11

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-19T15:16:09', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '8abe81ab-3cd7-408c-9d6d-e2711211027c' User entered '19 Aug 2020 15:16'	System	19 Aug 2020 19:16:11
	System	19 Aug 2020 19:16:11

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '19 Aug 2020 14:52'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '19 Aug 2020 17:22'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	19 Aug 2020 19:03:13
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-20T05:05:28', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '3a8a08c6-91aa-4fb9-ba38-8cca82220735' User entered 'Yes (Y)'	System	20 Aug 2020 09:05:56
	System	20 Aug 2020 09:05:56

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-20T05:05:43', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '3a8a08c6-91aa-4fb9-ba38-8cca82220735' User entered '97.4'	System	20 Aug 2020 09:05:56
	System	20 Aug 2020 09:05:56

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-20T05:05:47', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '3a8a08c6-91aa-4fb9-ba38-8cca82220735'	System	20 Aug 2020 09:05:56
User entered 'No (N)'	System	20 Aug 2020 09:05:56

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-20T05:05:54', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '3a8a08c6-91aa-4fb9-ba38-8cca82220735' User entered '20 Aug 2020 05:05'	System	20 Aug 2020 09:05:56
	System	20 Aug 2020 09:05:56

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '19 Aug 2020 18:17'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	19 Aug 2020 19:03:13
User entered 'Day 2'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:54

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-21T07:36:15', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'b92d195b-df77-465f-8ce2-06b2ec4fcff8'	System	21 Aug 2020 11:36:47
User entered 'Yes (Y)'	System	21 Aug 2020 11:36:47

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-21T07:36:28', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'b92d195b-df77-465f-8ce2-06b2ec4fcff8' User entered '97.2'	System	21 Aug 2020 11:36:47
	System	21 Aug 2020 11:36:47

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-21T07:36:36', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'b92d195b-df77-465f-8ce2-06b2ec4fcff8'	System	21 Aug 2020 11:36:47
User entered 'No (N)'	System	21 Aug 2020 11:36:47

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-21T07:36:45', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'b92d195b-df77-465f-8ce2-06b2ec4fcff8' User entered '21 Aug 2020 07:36'	System	21 Aug 2020 11:36:47
	System	21 Aug 2020 11:36:47

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	19 Aug 2020 19:03:13
User entered 'Day 3'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:22:54

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-22T06:59:56', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'a0931786-0430-447e-886a-66f0e66eebf8'	System	22 Aug 2020 11:00:19
User entered 'Yes (Y)'	System	22 Aug 2020 11:00:19

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:22:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-22T07:00:07', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'a0931786-0430-447e-886a-66f0e66eebf8' User entered '97.1'	System	22 Aug 2020 11:00:19
	System	22 Aug 2020 11:00:19

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-22T07:00:12', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'a0931786-0430-447e-886a-66f0e66eebf8'	System	22 Aug 2020 11:00:19
User entered 'No (N)'	System	22 Aug 2020 11:00:19

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:22:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-22T07:00:16', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'a0931786-0430-447e-886a-66f0e66eebf8'	System	22 Aug 2020 11:00:19
User entered '22 Aug 2020 07:00'	System	22 Aug 2020 11:00:19

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	19 Aug 2020 19:03:13
User entered 'Day 4'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:22:54

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-23T06:00:30', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '76a11b23-4aeb-4fba-b2e0-5e6e51f900f0' User entered 'Yes (Y)'	System	23 Aug 2020 10:00:56
	System	23 Aug 2020 10:00:56

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:22:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-23T06:00:39', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '76a11b23-4aeb-4fba-b2e0-5e6e51f900f0' User entered '97.2'	System	23 Aug 2020 10:00:56
	System	23 Aug 2020 10:00:56

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-23T06:00:44', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '76a11b23-4aeb-4fba-b2e0-5e6e51f900f0'	System	23 Aug 2020 10:00:56
User entered 'No (N)'	System	23 Aug 2020 10:00:56

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:22:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-23T06:00:51', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '76a11b23-4aeb-4fba-b2e0-5e6e51f900f0' User entered '23 Aug 2020 06:00'	System	23 Aug 2020 10:00:56
	System	23 Aug 2020 10:00:56

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	19 Aug 2020 19:03:13
User entered 'Day 5'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:54

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-24T06:12:21', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'eb1bd239-14e0-4713-a969-ac8b0d046e55'	System	24 Aug 2020 10:12:42
User entered 'Yes (Y)'	System	24 Aug 2020 10:12:42

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-24T06:12:30', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'eb1bd239-14e0-4713-a969-ac8b0d046e55' User entered '97.1'	System	24 Aug 2020 10:12:42
	System	24 Aug 2020 10:12:42

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-24T06:12:34', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'eb1bd239-14e0-4713-a969-ac8b0d046e55'	System	24 Aug 2020 10:12:42
User entered 'No (N)'	System	24 Aug 2020 10:12:42

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-24T06:12:38', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'eb1bd239-14e0-4713-a969-ac8b0d046e55'	System	24 Aug 2020 10:12:42
User entered '24 Aug 2020 06:12'	System	24 Aug 2020 10:12:42

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	19 Aug 2020 19:03:13
User entered 'Day 6'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:22:54

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-25T08:18:49', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '857ee90d-a9cd-4032-a1fa-9eaf6238ee43' User entered 'Yes (Y)'	System	25 Aug 2020 12:19:13
	System	25 Aug 2020 12:19:13

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:22:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-25T08:18:58', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '857ee90d-a9cd-4032-a1fa-9eaf6238ee43' User entered '97.2'	System	25 Aug 2020 12:19:13
	System	25 Aug 2020 12:19:13

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-25T08:19:03', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '857ee90d-a9cd-4032-a1fa-9eaf6238ee43'	System	25 Aug 2020 12:19:13
User entered 'No (N)'	System	25 Aug 2020 12:19:13

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:22:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-25T08:19:08', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '857ee90d-a9cd-4032-a1fa-9eaf6238ee43' User entered '25 Aug 2020 08:19'	System	25 Aug 2020 12:19:13
	System	25 Aug 2020 12:19:13

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	19 Aug 2020 19:03:13
User entered 'Day 7'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:22:54

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-26T07:55:28', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '84811d71-1ec4-47fb-a593-571036bff153'	System	26 Aug 2020 11:55:49
User entered 'Yes (Y)'	System	26 Aug 2020 11:55:49

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:22:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-26T07:55:38', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '84811d71-1ec4-47fb-a593-571036bff153' User entered '97.3'	System	26 Aug 2020 11:55:49
	System	26 Aug 2020 11:55:49

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-26T07:55:42', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '84811d71-1ec4-47fb-a593-571036bff153'	System	26 Aug 2020 11:55:49
User entered 'No (N)'	System	26 Aug 2020 11:55:49

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:22:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-26T07:55:45', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '84811d71-1ec4-47fb-a593-571036bff153'	System	26 Aug 2020 11:55:49
User entered '26 Aug 2020 07:55'	System	26 Aug 2020 11:55:49

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	19 Aug 2020 19:03:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-19T16:44:23', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'ef37af96-2fc4-429d-825d-4e650722dc55'	System	19 Aug 2020 20:45:10
User entered 'None (1)'	System	19 Aug 2020 20:45:10

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-19T16:44:36', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'ef37af96-2fc4-429d-825d-4e650722dc55'	System	19 Aug 2020 20:45:10
User entered 'No (N)'	System	19 Aug 2020 20:45:10

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-19T16:44:40', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'ef37af96-2fc4-429d-825d-4e650722dc55'	System	19 Aug 2020 20:45:10
User entered 'No (N)'	System	19 Aug 2020 20:45:10

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-19T16:44:52', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'ef37af96-2fc4-429d-825d-4e650722dc55'	System	19 Aug 2020 20:45:10
User entered 'None (1)'	System	19 Aug 2020 20:45:10

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-19T16:45:07', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'ef37af96-2fc4-429d-825d-4e650722dc55'	System	19 Aug 2020 20:45:10
User entered '19 Aug 2020 16:45'	System	19 Aug 2020 20:45:10

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '19 Aug 2020 14:52'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '19 Aug 2020 17:22'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	19 Aug 2020 19:03:13
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-20T05:06:04', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '74f0590a-4bbb-45b3-93ed-485f80576bd9' User entered 'None (1)'	System	20 Aug 2020 09:06:28
	System	20 Aug 2020 09:06:28

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-20T05:06:09', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '74f0590a-4bbb-45b3-93ed-485f80576bd9' User entered 'No (N)'	System	20 Aug 2020 09:06:28
	System	20 Aug 2020 09:06:28

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-20T05:06:13', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '74f0590a-4bbb-45b3-93ed-485f80576bd9' User entered 'No (N)'	System	20 Aug 2020 09:06:28
	System	20 Aug 2020 09:06:28

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-20T05:06:21', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '74f0590a-4bbb-45b3-93ed-485f80576bd9' User entered 'None (1)'	System	20 Aug 2020 09:06:28
	System	20 Aug 2020 09:06:28

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-20T05:06:25', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '74f0590a-4bbb-45b3-93ed-485f80576bd9' User entered '20 Aug 2020 05:06'	System	20 Aug 2020 09:06:28
	System	20 Aug 2020 09:06:28

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '19 Aug 2020 18:17'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	19 Aug 2020 19:03:13
User entered 'Day 2'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-21T07:36:55', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '8c0b2cc2-b5bb-4262-991d-7087e40475b3'	System	21 Aug 2020 11:37:24
User entered 'None (1)'	System	21 Aug 2020 11:37:24

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-21T07:37:01', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '8c0b2cc2-b5bb-4262-991d-7087e40475b3'	System	21 Aug 2020 11:37:24
User entered 'No (N)'	System	21 Aug 2020 11:37:24

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-21T07:37:07', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '8c0b2cc2-b5bb-4262-991d-7087e40475b3'	System	21 Aug 2020 11:37:24
User entered 'No (N)'	System	21 Aug 2020 11:37:24

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-21T07:37:13', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '8c0b2cc2-b5bb-4262-991d-7087e40475b3'	System	21 Aug 2020 11:37:24
User entered 'None (1)'	System	21 Aug 2020 11:37:24

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-21T07:37:21', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '8c0b2cc2-b5bb-4262-991d-7087e40475b3'	System	21 Aug 2020 11:37:24
User entered '21 Aug 2020 07:37'	System	21 Aug 2020 11:37:24

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	19 Aug 2020 19:03:13
User entered 'Day 3'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-22T07:00:24', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '64aa0c62-742a-4e78-9c78-8fe1b73d1ed4'	System	22 Aug 2020 11:00:45
User entered 'None (1)'	System	22 Aug 2020 11:00:45

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-22T07:00:28', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '64aa0c62-742a-4e78-9c78-8fe1b73d1ed4'	System	22 Aug 2020 11:00:45
User entered 'No (N)'	System	22 Aug 2020 11:00:45

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-22T07:00:32', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '64aa0c62-742a-4e78-9c78-8fe1b73d1ed4' User entered 'No (N)'	System	22 Aug 2020 11:00:45
	System	22 Aug 2020 11:00:45

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-22T07:00:38', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '64aa0c62-742a-4e78-9c78-8fe1b73d1ed4' User entered 'None (1)'	System	22 Aug 2020 11:00:45
	System	22 Aug 2020 11:00:45

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-22T07:00:43', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '64aa0c62-742a-4e78-9c78-8fe1b73d1ed4' User entered '22 Aug 2020 07:00'	System	22 Aug 2020 11:00:45
	System	22 Aug 2020 11:00:45

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	19 Aug 2020 19:03:13
User entered 'Day 4'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-23T06:00:59', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'adefb392-b5a9-491c-bd61-750acaf756cc'	System	23 Aug 2020 10:01:20
User entered 'None (1)'	System	23 Aug 2020 10:01:20

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-23T06:01:03', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'adefb392-b5a9-491c-bd61-750acaf756cc' User entered 'No (N)'	System	23 Aug 2020 10:01:20
	System	23 Aug 2020 10:01:20

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-23T06:01:08', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'adefb392-b5a9-491c-bd61-750acaf756cc'	System	23 Aug 2020 10:01:20
User entered 'No (N)'	System	23 Aug 2020 10:01:20

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-23T06:01:14', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'adefb392-b5a9-491c-bd61-750acaf756cc'	System	23 Aug 2020 10:01:20
User entered 'None (1)'	System	23 Aug 2020 10:01:20

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-23T06:01:17', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'adefb392-b5a9-491c-bd61-750acaf756cc' User entered '23 Aug 2020 06:01'	System	23 Aug 2020 10:01:20
	System	23 Aug 2020 10:01:20

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	19 Aug 2020 19:03:13
User entered 'Day 5'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-24T06:12:44', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '9ea567b6-d3e4-4474-bdd5-3778749c40fd' User entered 'None (1)'	System	24 Aug 2020 10:13:08
	System	24 Aug 2020 10:13:08

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-24T06:12:49', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '9ea567b6-d3e4-4474-bdd5-3778749c40fd' User entered 'No (N)'	System	24 Aug 2020 10:13:08
	System	24 Aug 2020 10:13:08

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-24T06:12:53', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '9ea567b6-d3e4-4474-bdd5-3778749c40fd' User entered 'No (N)'	System	24 Aug 2020 10:13:08
	System	24 Aug 2020 10:13:08

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-24T06:13:00', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '9ea567b6-d3e4-4474-bdd5-3778749c40fd' User entered 'None (1)'	System	24 Aug 2020 10:13:08
	System	24 Aug 2020 10:13:08

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-24T06:13:04', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '9ea567b6-d3e4-4474-bdd5-3778749c40fd' User entered '24 Aug 2020 06:13'	System	24 Aug 2020 10:13:08
	System	24 Aug 2020 10:13:08

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	19 Aug 2020 19:03:13
User entered 'Day 6'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-25T08:19:26', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '07e3a8a3-f909-4cb4-bfc9-3ca78134d1f7'	System	25 Aug 2020 12:19:42
User entered 'None (1)'	System	25 Aug 2020 12:19:42

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-25T08:19:29', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '07e3a8a3-f909-4cb4-bfc9-3ca78134d1f7'	System	25 Aug 2020 12:19:42
User entered 'No (N)'	System	25 Aug 2020 12:19:42

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-25T08:19:33', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '07e3a8a3-f909-4cb4-bfc9-3ca78134d1f7'	System	25 Aug 2020 12:19:42
User entered 'No (N)'	System	25 Aug 2020 12:19:42

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-25T08:19:36', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '07e3a8a3-f909-4cb4-bfc9-3ca78134d1f7'	System	25 Aug 2020 12:19:42
User entered 'None (1)'	System	25 Aug 2020 12:19:42

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-25T08:19:39', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '07e3a8a3-f909-4cb4-bfc9-3ca78134d1f7' User entered '25 Aug 2020 08:19'	System	25 Aug 2020 12:19:42
	System	25 Aug 2020 12:19:42

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	19 Aug 2020 19:03:13
User entered 'Day 7'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-26T07:55:51', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'c627eef4-9a63-4d77-aeec-f1a529e9d479' User entered 'None (1)'	System	26 Aug 2020 11:56:08
	System	26 Aug 2020 11:56:08

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-26T07:55:54', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'c627eef4-9a63-4d77-aeec-f1a529e9d479' User entered 'No (N)'	System	26 Aug 2020 11:56:08
	System	26 Aug 2020 11:56:08

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-26T07:55:58', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'c627eef4-9a63-4d77-aeec-f1a529e9d479'	System	26 Aug 2020 11:56:08
User entered 'No (N)'	System	26 Aug 2020 11:56:08

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-26T07:56:03', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'c627eef4-9a63-4d77-aeec-f1a529e9d479' User entered 'None (1)'	System	26 Aug 2020 11:56:08
	System	26 Aug 2020 11:56:08

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-26T07:56:06', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'c627eef4-9a63-4d77-aeec-f1a529e9d479' User entered '26 Aug 2020 07:56'	System	26 Aug 2020 11:56:08
	System	26 Aug 2020 11:56:08

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	19 Aug 2020 19:03:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-19T16:45:39', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'd1d4be94-1ec7-4d7c-8508-e7479b32ac91' User entered 'None (0)'	System	19 Aug 2020 20:46:20
	System	19 Aug 2020 20:46:20

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-19T16:45:46', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'd1d4be94-1ec7-4d7c-8508-e7479b32ac91' User entered 'None (0)'	System	19 Aug 2020 20:46:20
	System	19 Aug 2020 20:46:20

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-19T16:45:51', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'd1d4be94-1ec7-4d7c-8508-e7479b32ac91' User entered 'None (0)'	System	19 Aug 2020 20:46:20
	System	19 Aug 2020 20:46:20

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-19T16:45:55', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'd1d4be94-1ec7-4d7c-8508-e7479b32ac91' User entered 'None (0)'	System	19 Aug 2020 20:46:20
	System	19 Aug 2020 20:46:20

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-19T16:45:58', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'd1d4be94-1ec7-4d7c-8508-e7479b32ac91' User entered 'None (0)'	System	19 Aug 2020 20:46:20
	System	19 Aug 2020 20:46:20

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-19T16:46:03', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'd1d4be94-1ec7-4d7c-8508-e7479b32ac91' User entered 'None (0)'	System	19 Aug 2020 20:46:20
	System	19 Aug 2020 20:46:20

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-19T16:46:08', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'd1d4be94-1ec7-4d7c-8508-e7479b32ac91' User entered 'No (N)'	System	19 Aug 2020 20:46:20
	System	19 Aug 2020 20:46:20

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-19T16:46:16', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'd1d4be94-1ec7-4d7c-8508-e7479b32ac91' User entered '19 Aug 2020 16:46'	System	19 Aug 2020 20:46:20
	System	19 Aug 2020 20:46:20

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '19 Aug 2020 14:52'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '19 Aug 2020 17:22'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	19 Aug 2020 19:03:13
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-20T05:06:33', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'e3b30e93-ac9d-4522-af95-79fa7717d8a6' User entered 'None (0)'	System	20 Aug 2020 09:07:06
	System	20 Aug 2020 09:07:06

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-20T05:06:39', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'e3b30e93-ac9d-4522-af95-79fa7717d8a6' User entered 'None (0)'	System	20 Aug 2020 09:07:06
	System	20 Aug 2020 09:07:06

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-20T05:06:43', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'e3b30e93-ac9d-4522-af95-79fa7717d8a6' User entered 'None (0)'	System	20 Aug 2020 09:07:06
	System	20 Aug 2020 09:07:06

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-20T05:06:49', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'e3b30e93-ac9d-4522-af95-79fa7717d8a6' User entered 'None (0)'	System	20 Aug 2020 09:07:06
	System	20 Aug 2020 09:07:06

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-20T05:06:52', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'e3b30e93-ac9d-4522-af95-79fa7717d8a6' User entered 'None (0)'	System	20 Aug 2020 09:07:06
	System	20 Aug 2020 09:07:06

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-20T05:06:55', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'e3b30e93-ac9d-4522-af95-79fa7717d8a6' User entered 'None (0)'	System	20 Aug 2020 09:07:06
	System	20 Aug 2020 09:07:06

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-20T05:07:00', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'e3b30e93-ac9d-4522-af95-79fa7717d8a6' User entered 'No (N)'	System	20 Aug 2020 09:07:06
	System	20 Aug 2020 09:07:06

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-20T05:07:04', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'e3b30e93-ac9d-4522-af95-79fa7717d8a6' User entered '20 Aug 2020 05:07'	System	20 Aug 2020 09:07:06
	System	20 Aug 2020 09:07:06

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '19 Aug 2020 18:17'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	19 Aug 2020 19:03:13
User entered 'Day 2'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-21T07:37:30', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '73c8586c-b8e2-4517-91c0-c33748ddd136' User entered 'None (0)'	System	21 Aug 2020 11:38:12
	System	21 Aug 2020 11:38:12

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-21T07:37:35', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '73c8586c-b8e2-4517-91c0-c33748ddd136' User entered 'None (0)'	System	21 Aug 2020 11:38:12
	System	21 Aug 2020 11:38:12

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-21T07:37:40', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '73c8586c-b8e2-4517-91c0-c33748ddd136' User entered 'None (0)'	System	21 Aug 2020 11:38:12
	System	21 Aug 2020 11:38:12

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-21T07:37:45', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '73c8586c-b8e2-4517-91c0-c33748ddd136' User entered 'None (0)'	System	21 Aug 2020 11:38:12
	System	21 Aug 2020 11:38:12

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-21T07:37:51', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '73c8586c-b8e2-4517-91c0-c33748ddd136' User entered 'None (0)'	System	21 Aug 2020 11:38:12
	System	21 Aug 2020 11:38:12

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-21T07:37:59', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '73c8586c-b8e2-4517-91c0-c33748ddd136' User entered 'None (0)'	System	21 Aug 2020 11:38:12
	System	21 Aug 2020 11:38:12

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-21T07:38:04', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '73c8586c-b8e2-4517-91c0-c33748ddd136'	System	21 Aug 2020 11:38:12
User entered 'No (N)'	System	21 Aug 2020 11:38:12

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-21T07:38:09', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '73c8586c-b8e2-4517-91c0-c33748ddd136' User entered '21 Aug 2020 07:38'	System	21 Aug 2020 11:38:12
	System	21 Aug 2020 11:38:12

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	19 Aug 2020 19:03:13
User entered 'Day 3'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-22T07:00:52', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'b66a79de-a718-4163-9fff-ba4ddbfdc6f6' User entered 'None (0)'	System	22 Aug 2020 11:01:20
	System	22 Aug 2020 11:01:20

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-22T07:00:56', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'b66a79de-a718-4163-9fff-ba4ddbfdc6f6'	System	22 Aug 2020 11:01:20
User entered 'None (0)'	System	22 Aug 2020 11:01:20

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-22T07:01:00', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'b66a79de-a718-4163-9fff-ba4ddbfdc6f6' User entered 'None (0)'	System	22 Aug 2020 11:01:20
	System	22 Aug 2020 11:01:20

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-22T07:01:03', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'b66a79de-a718-4163-9fff-ba4ddbfdc6f6' User entered 'None (0)'	System	22 Aug 2020 11:01:20
	System	22 Aug 2020 11:01:20

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-22T07:01:08', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'b66a79de-a718-4163-9fff-ba4ddbfdc6f6' User entered 'None (0)'	System	22 Aug 2020 11:01:20
	System	22 Aug 2020 11:01:20

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-22T07:01:11', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'b66a79de-a718-4163-9fff-ba4ddbfdc6f6'	System	22 Aug 2020 11:01:20
User entered 'None (0)'	System	22 Aug 2020 11:01:20

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-22T07:01:15', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'b66a79de-a718-4163-9fff-ba4ddbfdc6f6'	System	22 Aug 2020 11:01:20
User entered 'No (N)'	System	22 Aug 2020 11:01:20

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-22T07:01:19', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'b66a79de-a718-4163-9fff-ba4ddbfdc6f6' User entered '22 Aug 2020 07:01'	System	22 Aug 2020 11:01:20
	System	22 Aug 2020 11:01:20

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	19 Aug 2020 19:03:13
User entered 'Day 4'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-23T06:01:29', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'cfc096ac-90c7-45fe-98ad-bb65ab054181' User entered 'None (0)'	System	23 Aug 2020 10:01:59
	System	23 Aug 2020 10:01:59

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-23T06:01:33', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'cfc096ac-90c7-45fe-98ad-bb65ab054181' User entered 'None (0)'	System	23 Aug 2020 10:01:59
	System	23 Aug 2020 10:01:59

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-23T06:01:37', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'cfc096ac-90c7-45fe-98ad-bb65ab054181' User entered 'None (0)'	System	23 Aug 2020 10:01:59
	System	23 Aug 2020 10:01:59

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-23T06:01:41', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'cfc096ac-90c7-45fe-98ad-bb65ab054181' User entered 'None (0)'	System	23 Aug 2020 10:01:59
	System	23 Aug 2020 10:01:59

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-23T06:01:44', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'cfc096ac-90c7-45fe-98ad-bb65ab054181' User entered 'None (0)'	System	23 Aug 2020 10:01:59
	System	23 Aug 2020 10:01:59

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-23T06:01:47', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'cfc096ac-90c7-45fe-98ad-bb65ab054181' User entered 'None (0)'	System	23 Aug 2020 10:01:59
	System	23 Aug 2020 10:01:59

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-23T06:01:52', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'cfc096ac-90c7-45fe-98ad-bb65ab054181'	System	23 Aug 2020 10:01:59
User entered 'No (N)'	System	23 Aug 2020 10:01:59

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-23T06:01:55', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'cfc096ac-90c7-45fe-98ad-bb65ab054181' User entered '23 Aug 2020 06:01'	System	23 Aug 2020 10:01:59
	System	23 Aug 2020 10:01:59

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	19 Aug 2020 19:03:13
User entered 'Day 5'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-24T06:13:16', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '45957f3b-300e-4d54-bf34-d2f1b9fafcfd' User entered 'None (0)'	System	24 Aug 2020 10:13:45
	System	24 Aug 2020 10:13:45

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-24T06:13:20', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '45957f3b-300e-4d54-bf34-d2f1b9fafcfd' User entered 'None (0)'	System	24 Aug 2020 10:13:45
	System	24 Aug 2020 10:13:45

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-24T06:13:23', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '45957f3b-300e-4d54-bf34-d2f1b9fafcfd' User entered 'None (0)'	System	24 Aug 2020 10:13:45
	System	24 Aug 2020 10:13:45

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-24T06:13:26', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '45957f3b-300e-4d54-bf34-d2f1b9fafcfd' User entered 'None (0)'	System	24 Aug 2020 10:13:45
	System	24 Aug 2020 10:13:45

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-24T06:13:30', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '45957f3b-300e-4d54-bf34-d2f1b9fafcfd' User entered 'None (0)'	System	24 Aug 2020 10:13:45
	System	24 Aug 2020 10:13:45

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-24T06:13:33', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '45957f3b-300e-4d54-bf34-d2f1b9fafcfd' User entered 'None (0)'	System	24 Aug 2020 10:13:45
	System	24 Aug 2020 10:13:45

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-24T06:13:39', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '45957f3b-300e-4d54-bf34-d2f1b9fafcfd' User entered 'No (N)'	System	24 Aug 2020 10:13:45
	System	24 Aug 2020 10:13:45

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-24T06:13:43', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '45957f3b-300e-4d54-bf34-d2f1b9fafcfd' User entered '24 Aug 2020 06:13'	System	24 Aug 2020 10:13:45
	System	24 Aug 2020 10:13:45

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	19 Aug 2020 19:03:13
User entered 'Day 6'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-25T08:19:45', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '20c267e8-4819-43bc-8bdd-967f18e3fe4e' User entered 'None (0)'	System	25 Aug 2020 12:20:12
	System	25 Aug 2020 12:20:12

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-25T08:19:49', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '20c267e8-4819-43bc-8bdd-967f18e3fe4e' User entered 'None (0)'	System	25 Aug 2020 12:20:12
	System	25 Aug 2020 12:20:12

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-25T08:19:53', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '20c267e8-4819-43bc-8bdd-967f18e3fe4e' User entered 'None (0)'	System	25 Aug 2020 12:20:12
	System	25 Aug 2020 12:20:12

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-25T08:19:57', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '20c267e8-4819-43bc-8bdd-967f18e3fe4e' User entered 'None (0)'	System	25 Aug 2020 12:20:12
	System	25 Aug 2020 12:20:12

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-25T08:20:00', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '20c267e8-4819-43bc-8bdd-967f18e3fe4e' User entered 'None (0)'	System	25 Aug 2020 12:20:12
	System	25 Aug 2020 12:20:12

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-25T08:20:02', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '20c267e8-4819-43bc-8bdd-967f18e3fe4e' User entered 'None (0)'	System	25 Aug 2020 12:20:12
	System	25 Aug 2020 12:20:12

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-25T08:20:07', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '20c267e8-4819-43bc-8bdd-967f18e3fe4e' User entered 'No (N)'	System	25 Aug 2020 12:20:12
	System	25 Aug 2020 12:20:12

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-25T08:20:10', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '20c267e8-4819-43bc-8bdd-967f18e3fe4e' User entered '25 Aug 2020 08:20'	System	25 Aug 2020 12:20:12
	System	25 Aug 2020 12:20:12

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	19 Aug 2020 19:03:13
User entered 'Day 7'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-26T07:56:10', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '06a9a57e-3899-41e6-9722-309498c6b867' User entered 'None (0)'	System	26 Aug 2020 11:56:34
	System	26 Aug 2020 11:56:34

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-26T07:56:13', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '06a9a57e-3899-41e6-9722-309498c6b867' User entered 'None (0)'	System	26 Aug 2020 11:56:34
	System	26 Aug 2020 11:56:34

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-26T07:56:15', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '06a9a57e-3899-41e6-9722-309498c6b867' User entered 'None (0)'	System	26 Aug 2020 11:56:34
	System	26 Aug 2020 11:56:34

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-26T07:56:18', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '06a9a57e-3899-41e6-9722-309498c6b867' User entered 'None (0)'	System	26 Aug 2020 11:56:34
	System	26 Aug 2020 11:56:34

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-26T07:56:21', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '06a9a57e-3899-41e6-9722-309498c6b867' User entered 'None (0)'	System	26 Aug 2020 11:56:34
	System	26 Aug 2020 11:56:34

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-26T07:56:23', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '06a9a57e-3899-41e6-9722-309498c6b867' User entered 'None (0)'	System	26 Aug 2020 11:56:34
	System	26 Aug 2020 11:56:34

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-26T07:56:27', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '06a9a57e-3899-41e6-9722-309498c6b867'	System	26 Aug 2020 11:56:34
User entered 'No (N)'	System	26 Aug 2020 11:56:34

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-08-26T07:56:30', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '06a9a57e-3899-41e6-9722-309498c6b867'	System	26 Aug 2020 11:56:34
User entered '26 Aug 2020 07:56'	System	26 Aug 2020 11:56:34

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 19:03:13

US3672199

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 19:03:13

US3672199

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 20:53:54

US3672199

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '26 Aug 2020'	(b) (4), (b) (6)	26 Aug 2020 20:53:54

US3672199

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	26 Aug 2020 20:53:54

US3672199

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 20:53:54

US3672199

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 20:53:57

US3672199

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered 'I'	System	26 Aug 2020 20:53:57

US3672199

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Sep 2020 17:50:26

US3672199

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '04 Sep 2020'	(b) (4), (b) (6)	12 Sep 2020 17:50:26

US3672199

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Sep 2020 17:50:26

US3672199

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty.	(b) (4), (b) (6)	12 Sep 2020 17:50:26

US3672199

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Sep 2020 17:50:31

US3672199

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered 'I'	System	12 Sep 2020 17:50:31

US3672199

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Sep 2020 17:50:44

US3672199

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '11 Sep 2020'	(b) (4), (b) (6)	12 Sep 2020 17:50:44

US3672199

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Sep 2020 17:50:44

US3672199

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty.	(b) (4), (b) (6)	12 Sep 2020 17:50:44

US3672199

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Sep 2020 17:50:48

US3672199

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered 'I'	System	12 Sep 2020 17:50:48

US3672199

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 19:36:05

US3672199

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 19:36:05

US3672199

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 19:36:05

US3672199

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered 'VISIT2'	System	23 Sep 2020 19:36:05

US3672199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	23 Sep 2020 19:42:42

US3672199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 19:42:42

US3672199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 19:42:42

US3672199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '14:48'	(b) (4), (b) (6)	23 Sep 2020 19:42:42

US3672199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered '18 Sep 2020 14:48'	System	23 Sep 2020 19:42:42

US3672199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '97.8' F	(b) (4), (b) (6)	23 Sep 2020 19:42:42

US3672199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Oral (Oral)'	(b) (4), (b) (6)	23 Sep 2020 19:42:42

US3672199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 19:42:42

US3672199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '78'	(b) (4), (b) (6)	23 Sep 2020 19:42:42

US3672199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered 'bpm'	System	23 Sep 2020 19:42:42

US3672199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '16'	(b) (4), (b) (6)	23 Sep 2020 19:42:42

US3672199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered 'breaths/min'	System	23 Sep 2020 19:42:42

US3672199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '124'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 19:42:42

US3672199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered 'mmHg'	System	23 Sep 2020 19:42:42

US3672199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '72'	(b) (4), (b) (6)	23 Sep 2020 19:42:42

US3672199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered 'mmHg'	System	23 Sep 2020 19:42:42

US3672199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	23 Sep 2020 19:44:42

US3672199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 19:44:42

US3672199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '18 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 19:44:42

US3672199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '16:00'	(b) (4), (b) (6)	23 Sep 2020 19:44:42

US3672199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered '18 Sep 2020 16:00'	System	23 Sep 2020 19:44:42

US3672199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '97.7' F	(b) (4), (b) (6)	23 Sep 2020 19:44:42

US3672199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Oral (Oral)'	(b) (4), (b) (6)	23 Sep 2020 19:44:42

US3672199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 19:44:42

US3672199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '80'	(b) (4), (b) (6)	23 Sep 2020 19:44:42

US3672199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered 'bpm'	System	23 Sep 2020 19:44:42

US3672199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '16'	(b) (4), (b) (6)	23 Sep 2020 19:44:42

US3672199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered 'breaths/min'	System	23 Sep 2020 19:44:42

US3672199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '124'	(b) (4), (b) (6)	23 Sep 2020 19:44:42

US3672199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered 'mmHg'	System	23 Sep 2020 19:44:42

US3672199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '69'	(b) (4), (b) (6)	23 Sep 2020 19:44:42

US3672199

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered 'mmHg'	System	23 Sep 2020 19:44:42

US3672199

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 19:44:51

US3672199

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '18 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 19:44:51

US3672199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:40:35

US3672199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:54

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 19:40:35

US3672199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 19:40:35

US3672199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:54

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered 'MRNA-1273 OR PLACEBO'	System	18 Sep 2020 19:40:35

US3672199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:54

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:40:35

US3672199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:54

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '15:26'	(b) (4), (b) (6)	18 Sep 2020 19:40:35

US3672199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:54

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered '18 Sep 2020 15:26'	System	18 Sep 2020 19:40:35

US3672199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:54

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 19:40:35

US3672199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:54

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered 'ONCE'	System	18 Sep 2020 19:40:35

US3672199

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:54

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered 'INTRAMUSCULAR'	System	18 Sep 2020 19:40:35

US3672199

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 19:45:13

US3672199

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '18 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 19:45:13

US3672199

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:54

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '15:02'	(b) (4), (b) (6)	23 Sep 2020 19:45:13

US3672199

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered '18 Sep 2020 15:02'	System	23 Sep 2020 19:45:13

US3672199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:22:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '18 Sep 2020'	(b) (4), (b) (6)	23 Sep 2020 19:45:26

US3672199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:22:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	23 Sep 2020 19:45:26

US3672199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:22:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 19:45:26

US3672199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:22:54

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '14:55'	(b) (4), (b) (6)	23 Sep 2020 19:45:26

US3672199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:22:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered '18 Sep 2020 14:55'	System	23 Sep 2020 19:45:26

US3672199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:22:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	23 Sep 2020 19:45:26

US3672199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:22:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 19:45:26

US3672199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:22:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 19:45:26

US3672199

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:22:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered empty.	System	23 Sep 2020 19:45:26

US3672199

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 19:47:23

US3672199

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered '1'	System	23 Sep 2020 19:47:23

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	18 Sep 2020 19:40:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-18T15:59:12', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'e47aa769-7cdc-4075-96e9-1cd609af9812' User entered 'Yes (Y)'	System	18 Sep 2020 19:59:44
	System	18 Sep 2020 19:59:44

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-18T15:59:27', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'e47aa769-7cdc-4075-96e9-1cd609af9812' User entered '97.7'	System	18 Sep 2020 19:59:44
	System	18 Sep 2020 19:59:44

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-18T15:59:31', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'e47aa769-7cdc-4075-96e9-1cd609af9812'	System	18 Sep 2020 19:59:44
User entered 'No (N)'	System	18 Sep 2020 19:59:44

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-18T15:59:39', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'e47aa769-7cdc-4075-96e9-1cd609af9812'	System	18 Sep 2020 19:59:44
User entered '18 Sep 2020 15:59'	System	18 Sep 2020 19:59:44

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '18 Sep 2020 15:46'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '18 Sep 2020 18:16'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	18 Sep 2020 19:40:35
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-19T07:46:14', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '1a401575-b3cc-4720-8d2a-16b4eb753eda' User entered 'Yes (Y)'	System	19 Sep 2020 11:46:37
	System	19 Sep 2020 11:46:37

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-19T07:46:26', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '1a401575-b3cc-4720-8d2a-16b4eb753eda' User entered '97.3'	System	19 Sep 2020 11:46:37
	System	19 Sep 2020 11:46:37

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-19T07:46:30', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '1a401575-b3cc-4720-8d2a-16b4eb753eda' User entered 'No (N)'	System	19 Sep 2020 11:46:37
	System	19 Sep 2020 11:46:37

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-19T07:46:34', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '1a401575-b3cc-4720-8d2a-16b4eb753eda' User entered '19 Sep 2020 07:46'	System	19 Sep 2020 11:46:37
	System	19 Sep 2020 11:46:37

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '18 Sep 2020 19:11'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	18 Sep 2020 19:40:35
User entered 'Day 2'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:54

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-19T22:16:10', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '233c2719-982e-4fd5-b4b7-7c8d60e75e4e' User entered 'Yes (Y)'	System	20 Sep 2020 02:16:33
	System	20 Sep 2020 02:16:33

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-19T22:16:20', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '233c2719-982e-4fd5-b4b7-7c8d60e75e4e' User entered '97.2'	System	20 Sep 2020 02:16:33
	System	20 Sep 2020 02:16:33

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-19T22:16:25', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '233c2719-982e-4fd5-b4b7-7c8d60e75e4e' User entered 'No (N)'	System	20 Sep 2020 02:16:33
	System	20 Sep 2020 02:16:33

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-19T22:16:29', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '233c2719-982e-4fd5-b4b7-7c8d60e75e4e' User entered '19 Sep 2020 22:16'	System	20 Sep 2020 02:16:33
	System	20 Sep 2020 02:16:33

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	18 Sep 2020 19:40:35
User entered 'Day 3'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:22:54

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-20T17:52:56', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '35d400d1-f579-49b7-830c-b536d80e1fe0' User entered 'Yes (Y)'	System	20 Sep 2020 21:53:16
	System	20 Sep 2020 21:53:16

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:22:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-20T17:53:05', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '35d400d1-f579-49b7-830c-b536d80e1fe0' User entered '97.3'	System	20 Sep 2020 21:53:16
	System	20 Sep 2020 21:53:16

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-20T17:53:10', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '35d400d1-f579-49b7-830c-b536d80e1fe0'	System	20 Sep 2020 21:53:16
User entered 'No (N)'	System	20 Sep 2020 21:53:16

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:22:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-20T17:53:13', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '35d400d1-f579-49b7-830c-b536d80e1fe0' User entered '20 Sep 2020 17:53'	System	20 Sep 2020 21:53:16
	System	20 Sep 2020 21:53:16

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	18 Sep 2020 19:40:35
User entered 'Day 4'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:22:54

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-21T16:09:34', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '825b14f8-4892-4a03-87dd-ca324fd85fc9' User entered 'Yes (Y)'	System	21 Sep 2020 20:09:53
	System	21 Sep 2020 20:09:53

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:22:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-21T16:09:43', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '825b14f8-4892-4a03-87dd-ca324fd85fc9' User entered '97.5'	System	21 Sep 2020 20:09:53
	System	21 Sep 2020 20:09:53

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-21T16:09:47', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '825b14f8-4892-4a03-87dd-ca324fd85fc9'	System	21 Sep 2020 20:09:53
User entered 'No (N)'	System	21 Sep 2020 20:09:53

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:22:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-21T16:09:50', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '825b14f8-4892-4a03-87dd-ca324fd85fc9' User entered '21 Sep 2020 16:09'	System	21 Sep 2020 20:09:53
	System	21 Sep 2020 20:09:53

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	18 Sep 2020 19:40:35
User entered 'Day 5'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:54

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-23T05:58:38', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '19a6611c-5f26-4247-b885-30f0b6246430' User entered 'Yes (Y)'	System	23 Sep 2020 09:59:00
	System	23 Sep 2020 09:59:00

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-23T05:58:48', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '19a6611c-5f26-4247-b885-30f0b6246430' User entered '97.5'	System	23 Sep 2020 09:59:00
	System	23 Sep 2020 09:59:00

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-23T05:58:52', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '19a6611c-5f26-4247-b885-30f0b6246430' User entered 'No (N)'	System	23 Sep 2020 09:59:00
	System	23 Sep 2020 09:59:00

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-23T05:58:55', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '19a6611c-5f26-4247-b885-30f0b6246430' User entered '23 Sep 2020 05:58'	System	23 Sep 2020 09:59:00
	System	23 Sep 2020 09:59:00

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	18 Sep 2020 19:40:35
User entered 'Day 6'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:22:54

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-23T20:39:22', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '5fd725ae-5115-42ee-a806-a18112885011' User entered 'Yes (Y)'	System	24 Sep 2020 00:39:40
	System	24 Sep 2020 00:39:40

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:22:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-23T20:39:30', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '5fd725ae-5115-42ee-a806-a18112885011' User entered '97.4'	System	24 Sep 2020 00:39:40
	System	24 Sep 2020 00:39:40

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-23T20:39:35', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '5fd725ae-5115-42ee-a806-a18112885011' User entered 'No (N)'	System	24 Sep 2020 00:39:40
	System	24 Sep 2020 00:39:40

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:22:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-23T20:39:38', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '5fd725ae-5115-42ee-a806-a18112885011' User entered '23 Sep 2020 20:39'	System	24 Sep 2020 00:39:40
	System	24 Sep 2020 00:39:40

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	18 Sep 2020 19:40:35
User entered 'Day 7'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:22:54

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-25T02:59:44', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '4191636b-08a9-4de9-bee8-babc7b1b9d9b' User entered 'Yes (Y)'	System	25 Sep 2020 07:00:08
	System	25 Sep 2020 07:00:08

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:22:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-25T02:59:55', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '4191636b-08a9-4de9-bee8-babc7b1b9d9b' User entered '97.4'	System	25 Sep 2020 07:00:08
	System	25 Sep 2020 07:00:08

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-25T02:59:59', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '4191636b-08a9-4de9-bee8-babc7b1b9d9b' User entered 'No (N)'	System	25 Sep 2020 07:00:08
	System	25 Sep 2020 07:00:08

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:22:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-25T03:00:03', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '4191636b-08a9-4de9-bee8-babc7b1b9d9b' User entered '25 Sep 2020 03:00'	System	25 Sep 2020 07:00:08
	System	25 Sep 2020 07:00:08

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	18 Sep 2020 19:40:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-18T15:59:45', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '656291e9-bc33-4ba7-a963-dcec0fe97a3e'	System	18 Sep 2020 20:00:06
User entered 'None (1)'	System	18 Sep 2020 20:00:06

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-18T15:59:50', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '656291e9-bc33-4ba7-a963-dcec0fe97a3e' User entered 'No (N)'	System	18 Sep 2020 20:00:06
	System	18 Sep 2020 20:00:06

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-18T15:59:53', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '656291e9-bc33-4ba7-a963-dcec0fe97a3e' User entered 'No (N)'	System	18 Sep 2020 20:00:06
	System	18 Sep 2020 20:00:06

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-18T15:59:58', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '656291e9-bc33-4ba7-a963-dcec0fe97a3e' User entered 'None (1)'	System	18 Sep 2020 20:00:06
	System	18 Sep 2020 20:00:06

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-18T16:00:02', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '656291e9-bc33-4ba7-a963-dcec0fe97a3e' User entered '18 Sep 2020 16:00'	System	18 Sep 2020 20:00:06
	System	18 Sep 2020 20:00:06

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '18 Sep 2020 15:46'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '18 Sep 2020 18:16'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	18 Sep 2020 19:40:35
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-19T07:45:50', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'a4c4e674-ed56-4e9c-b488-25bd9718ca56'	System	19 Sep 2020 11:46:11
User entered 'None (1)'	System	19 Sep 2020 11:46:11

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-19T07:45:54', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'a4c4e674-ed56-4e9c-b488-25bd9718ca56' User entered 'No (N)'	System	19 Sep 2020 11:46:11
	System	19 Sep 2020 11:46:11

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-19T07:45:57', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'a4c4e674-ed56-4e9c-b488-25bd9718ca56'	System	19 Sep 2020 11:46:11
User entered 'No (N)'	System	19 Sep 2020 11:46:11

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-19T07:46:01', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'a4c4e674-ed56-4e9c-b488-25bd9718ca56'	System	19 Sep 2020 11:46:11
User entered 'None (1)'	System	19 Sep 2020 11:46:11

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-19T07:46:05', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'a4c4e674-ed56-4e9c-b488-25bd9718ca56' User entered '19 Sep 2020 07:46'	System	19 Sep 2020 11:46:11
	System	19 Sep 2020 11:46:11

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '18 Sep 2020 19:11'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	18 Sep 2020 19:40:35
User entered 'Day 2'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-19T22:16:34', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '03db9fdb-243f-4fc6-bbc8-70a313d8362a' User entered 'None (1)'	System	20 Sep 2020 02:16:56
	System	20 Sep 2020 02:16:56

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-19T22:16:38', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '03db9fdb-243f-4fc6-bbc8-70a313d8362a' User entered 'No (N)'	System	20 Sep 2020 02:16:56
	System	20 Sep 2020 02:16:56

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-19T22:16:43', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '03db9fdb-243f-4fc6-bbc8-70a313d8362a' User entered 'No (N)'	System	20 Sep 2020 02:16:56
	System	20 Sep 2020 02:16:56

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-19T22:16:51', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '03db9fdb-243f-4fc6-bbc8-70a313d8362a' User entered 'None (1)'	System	20 Sep 2020 02:16:56
	System	20 Sep 2020 02:16:56

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-19T22:16:54', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '03db9fdb-243f-4fc6-bbc8-70a313d8362a' User entered '19 Sep 2020 22:16'	System	20 Sep 2020 02:16:56
	System	20 Sep 2020 02:16:56

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	18 Sep 2020 19:40:35
User entered 'Day 3'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-20T17:53:17', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'adc7d1d4-7551-42fc-beec-71493985ddd5'	System	20 Sep 2020 21:53:35
User entered 'None (1)'	System	20 Sep 2020 21:53:35

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-20T17:53:21', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'adc7d1d4-7551-42fc-beec-71493985ddd5' User entered 'No (N)'	System	20 Sep 2020 21:53:35
	System	20 Sep 2020 21:53:35

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-20T17:53:25', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'adc7d1d4-7551-42fc-beec-71493985ddd5' User entered 'No (N)'	System	20 Sep 2020 21:53:35
	System	20 Sep 2020 21:53:35

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-20T17:53:31', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'adc7d1d4-7551-42fc-beec-71493985ddd5'	System	20 Sep 2020 21:53:35
User entered 'None (1)'	System	20 Sep 2020 21:53:35

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-20T17:53:34', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'adc7d1d4-7551-42fc-beec-71493985ddd5' User entered '20 Sep 2020 17:53'	System	20 Sep 2020 21:53:35
	System	20 Sep 2020 21:53:35

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	18 Sep 2020 19:40:35
User entered 'Day 4'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-21T16:09:55', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '586019fe-ad95-4f68-acf2-5bf50f8fa1db'	System	21 Sep 2020 20:10:11
User entered 'None (1)'	System	21 Sep 2020 20:10:11

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-21T16:09:58', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '586019fe-ad95-4f68-acf2-5bf50f8fa1db'	System	21 Sep 2020 20:10:11
User entered 'No (N)'	System	21 Sep 2020 20:10:11

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-21T16:10:02', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '586019fe-ad95-4f68-acf2-5bf50f8fa1db' User entered 'No (N)'	System	21 Sep 2020 20:10:11
	System	21 Sep 2020 20:10:11

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-21T16:10:04', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '586019fe-ad95-4f68-acf2-5bf50f8fa1db'	System	21 Sep 2020 20:10:11
User entered 'None (1)'	System	21 Sep 2020 20:10:11

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-21T16:10:07', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '586019fe-ad95-4f68-acf2-5bf50f8fa1db'	System	21 Sep 2020 20:10:11
User entered '21 Sep 2020 16:10'	System	21 Sep 2020 20:10:11

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	18 Sep 2020 19:40:35
User entered 'Day 5'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-23T05:59:00', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '3361f48c-4975-4ee8-8903-ca158b28f4fb' User entered 'None (1)'	System	23 Sep 2020 09:59:23
	System	23 Sep 2020 09:59:23

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-23T05:59:09', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '3361f48c-4975-4ee8-8903-ca158b28f4fb' User entered 'No (N)'	System	23 Sep 2020 09:59:23
	System	23 Sep 2020 09:59:23

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-23T05:59:13', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '3361f48c-4975-4ee8-8903-ca158b28f4fb' User entered 'No (N)'	System	23 Sep 2020 09:59:23
	System	23 Sep 2020 09:59:23

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-23T05:59:17', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '3361f48c-4975-4ee8-8903-ca158b28f4fb' User entered 'None (1)'	System	23 Sep 2020 09:59:23
	System	23 Sep 2020 09:59:23

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-23T05:59:20', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '3361f48c-4975-4ee8-8903-ca158b28f4fb' User entered '23 Sep 2020 05:59'	System	23 Sep 2020 09:59:23
	System	23 Sep 2020 09:59:23

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	18 Sep 2020 19:40:35
User entered 'Day 6'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-23T20:39:42', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '2d4e84a0-b10c-4dbf-ad93-cedef7dcec4a' User entered 'None (1)'	System	24 Sep 2020 00:39:58
	System	24 Sep 2020 00:39:58

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-23T20:39:46', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '2d4e84a0-b10c-4dbf-ad93-cedef7dcec4a' User entered 'No (N)'	System	24 Sep 2020 00:39:58
	System	24 Sep 2020 00:39:58

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-23T20:39:50', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '2d4e84a0-b10c-4dbf-ad93-cedef7dcec4a' User entered 'No (N)'	System	24 Sep 2020 00:39:58
	System	24 Sep 2020 00:39:58

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-23T20:39:52', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '2d4e84a0-b10c-4dbf-ad93-ceedef7dcec4a' User entered 'None (1)'	System	24 Sep 2020 00:39:58
	System	24 Sep 2020 00:39:58

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-23T20:39:55', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '2d4e84a0-b10c-4dbf-ad93-ceedef7dcec4a' User entered '23 Sep 2020 20:39'	System	24 Sep 2020 00:39:58
	System	24 Sep 2020 00:39:58

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	18 Sep 2020 19:40:35
User entered 'Day 7'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-25T03:00:08', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'b58ea255-5c2f-4fa6-8a58-9be3381701c0'	System	25 Sep 2020 07:00:27
User entered 'None (1)'	System	25 Sep 2020 07:00:27

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-25T03:00:12', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'b58ea255-5c2f-4fa6-8a58-9be3381701c0' User entered 'No (N)'	System	25 Sep 2020 07:00:27
	System	25 Sep 2020 07:00:27

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-25T03:00:15', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'b58ea255-5c2f-4fa6-8a58-9be3381701c0' User entered 'No (N)'	System	25 Sep 2020 07:00:27
	System	25 Sep 2020 07:00:27

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-25T03:00:19', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'b58ea255-5c2f-4fa6-8a58-9be3381701c0'	System	25 Sep 2020 07:00:27
User entered 'None (1)'	System	25 Sep 2020 07:00:27

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-25T03:00:22', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'b58ea255-5c2f-4fa6-8a58-9be3381701c0' User entered '25 Sep 2020 03:00'	System	25 Sep 2020 07:00:27
	System	25 Sep 2020 07:00:27

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	18 Sep 2020 19:40:35
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-18T16:00:10', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '820ef50d-504e-489c-ad7c-fc87b8d151ff' User entered 'None (0)'	System	18 Sep 2020 20:00:38
	System	18 Sep 2020 20:00:38

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-18T16:00:13', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '820ef50d-504e-489c-ad7c-fc87b8d151ff' User entered 'None (0)'	System	18 Sep 2020 20:00:38
	System	18 Sep 2020 20:00:38

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-18T16:00:16', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '820ef50d-504e-489c-ad7c-fc87b8d151ff' User entered 'None (0)'	System	18 Sep 2020 20:00:38
	System	18 Sep 2020 20:00:38

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-18T16:00:21', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '820ef50d-504e-489c-ad7c-fc87b8d151ff' User entered 'None (0)'	System	18 Sep 2020 20:00:38
	System	18 Sep 2020 20:00:38

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-18T16:00:24', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '820ef50d-504e-489c-ad7c-fc87b8d151ff' User entered 'None (0)'	System	18 Sep 2020 20:00:38
	System	18 Sep 2020 20:00:38

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-18T16:00:27', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '820ef50d-504e-489c-ad7c-fc87b8d151ff' User entered 'None (0)'	System	18 Sep 2020 20:00:38
	System	18 Sep 2020 20:00:38

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-18T16:00:32', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '820ef50d-504e-489c-ad7c-fc87b8d151ff' User entered 'No (N)'	System	18 Sep 2020 20:00:38
	System	18 Sep 2020 20:00:38

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-18T16:00:35', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '820ef50d-504e-489c-ad7c-fc87b8d151ff' User entered '18 Sep 2020 16:00'	System	18 Sep 2020 20:00:38
	System	18 Sep 2020 20:00:38

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '18 Sep 2020 15:46'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '18 Sep 2020 18:16'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	18 Sep 2020 19:40:35
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-19T07:46:40', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'd2ba021b-9085-4a75-8e0f-f947e8ce9943' User entered 'None (0)'	System	19 Sep 2020 11:47:06
	System	19 Sep 2020 11:47:06

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-19T07:46:42', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'd2ba021b-9085-4a75-8e0f-f947e8ce9943' User entered 'None (0)'	System	19 Sep 2020 11:47:06
	System	19 Sep 2020 11:47:06

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-19T07:46:45', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'd2ba021b-9085-4a75-8e0f-f947e8ce9943' User entered 'None (0)'	System	19 Sep 2020 11:47:06
	System	19 Sep 2020 11:47:06

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-19T07:46:48', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'd2ba021b-9085-4a75-8e0f-f947e8ce9943' User entered 'None (0)'	System	19 Sep 2020 11:47:06
	System	19 Sep 2020 11:47:06

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-19T07:46:50', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'd2ba021b-9085-4a75-8e0f-f947e8ce9943' User entered 'None (0)'	System	19 Sep 2020 11:47:06
	System	19 Sep 2020 11:47:06

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-19T07:46:54', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'd2ba021b-9085-4a75-8e0f-f947e8ce9943' User entered 'None (0)'	System	19 Sep 2020 11:47:06
	System	19 Sep 2020 11:47:06

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-19T07:46:59', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'd2ba021b-9085-4a75-8e0f-f947e8ce9943'	System	19 Sep 2020 11:47:06
User entered 'No (N)'	System	19 Sep 2020 11:47:06

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-19T07:47:02', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'd2ba021b-9085-4a75-8e0f-f947e8ce9943' User entered '19 Sep 2020 07:47'	System	19 Sep 2020 11:47:06
	System	19 Sep 2020 11:47:06

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '18 Sep 2020 19:11'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	18 Sep 2020 19:40:35
User entered 'Day 2'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-19T22:16:59', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '3a1751b6-9f7f-4697-adad-c284f3bc4cba' User entered 'None (0)'	System	20 Sep 2020 02:17:23
	System	20 Sep 2020 02:17:23

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-19T22:17:01', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '3a1751b6-9f7f-4697-adad-c284f3bc4cba' User entered 'None (0)'	System	20 Sep 2020 02:17:23
	System	20 Sep 2020 02:17:23

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-19T22:17:04', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '3a1751b6-9f7f-4697-adad-c284f3bc4cba' User entered 'None (0)'	System	20 Sep 2020 02:17:23
	System	20 Sep 2020 02:17:23

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-19T22:17:06', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '3a1751b6-9f7f-4697-adad-c284f3bc4cba' User entered 'None (0)'	System	20 Sep 2020 02:17:23
	System	20 Sep 2020 02:17:23

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-19T22:17:08', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '3a1751b6-9f7f-4697-adad-c284f3bc4cba' User entered 'None (0)'	System	20 Sep 2020 02:17:23
	System	20 Sep 2020 02:17:23

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-19T22:17:12', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '3a1751b6-9f7f-4697-adad-c284f3bc4cba' User entered 'None (0)'	System	20 Sep 2020 02:17:23
	System	20 Sep 2020 02:17:23

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-19T22:17:16', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '3a1751b6-9f7f-4697-adad-c284f3bc4cba' User entered 'No (N)'	System	20 Sep 2020 02:17:23
	System	20 Sep 2020 02:17:23

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-19T22:17:19', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '3a1751b6-9f7f-4697-adad-c284f3bc4cba' User entered '19 Sep 2020 22:17'	System	20 Sep 2020 02:17:23
	System	20 Sep 2020 02:17:23

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	18 Sep 2020 19:40:35
User entered 'Day 3'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-20T17:53:39', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '39addbbd-9727-4403-bf63-f79108f4a7b1' User entered 'None (0)'	System	20 Sep 2020 21:54:05
	System	20 Sep 2020 21:54:05

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-20T17:53:42', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '39addbbd-9727-4403-bf63-f79108f4a7b1' User entered 'None (0)'	System	20 Sep 2020 21:54:05
	System	20 Sep 2020 21:54:05

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-20T17:53:46', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '39addbbd-9727-4403-bf63-f79108f4a7b1' User entered 'None (0)'	System	20 Sep 2020 21:54:05
	System	20 Sep 2020 21:54:05

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-20T17:53:49', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '39addbbd-9727-4403-bf63-f79108f4a7b1' User entered 'None (0)'	System	20 Sep 2020 21:54:05
	System	20 Sep 2020 21:54:05

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-20T17:53:51', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '39addbbd-9727-4403-bf63-f79108f4a7b1' User entered 'None (0)'	System	20 Sep 2020 21:54:05
	System	20 Sep 2020 21:54:05

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-20T17:53:55', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '39addbbd-9727-4403-bf63-f79108f4a7b1' User entered 'None (0)'	System	20 Sep 2020 21:54:05
	System	20 Sep 2020 21:54:05

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-20T17:53:59', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '39addbbd-9727-4403-bf63-f79108f4a7b1' User entered 'No (N)'	System	20 Sep 2020 21:54:05
	System	20 Sep 2020 21:54:05

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-20T17:54:04', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '39addbbd-9727-4403-bf63-f79108f4a7b1' User entered '20 Sep 2020 17:54'	System	20 Sep 2020 21:54:05
	System	20 Sep 2020 21:54:05

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	18 Sep 2020 19:40:35
User entered 'Day 4'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-21T16:10:12', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '4dc81063-44bf-4e5e-bf60-c13102f85e19' User entered 'None (0)'	System	21 Sep 2020 20:10:37
	System	21 Sep 2020 20:10:37

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-21T16:10:15', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '4dc81063-44bf-4e5e-bf60-c13102f85e19' User entered 'None (0)'	System	21 Sep 2020 20:10:37
	System	21 Sep 2020 20:10:37

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-21T16:10:17', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '4dc81063-44bf-4e5e-bf60-c13102f85e19' User entered 'None (0)'	System	21 Sep 2020 20:10:37
	System	21 Sep 2020 20:10:37

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-21T16:10:21', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '4dc81063-44bf-4e5e-bf60-c13102f85e19' User entered 'None (0)'	System	21 Sep 2020 20:10:37
	System	21 Sep 2020 20:10:37

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-21T16:10:25', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '4dc81063-44bf-4e5e-bf60-c13102f85e19' User entered 'None (0)'	System	21 Sep 2020 20:10:37
	System	21 Sep 2020 20:10:37

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-21T16:10:27', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '4dc81063-44bf-4e5e-bf60-c13102f85e19' User entered 'None (0)'	System	21 Sep 2020 20:10:37
	System	21 Sep 2020 20:10:37

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-21T16:10:31', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '4dc81063-44bf-4e5e-bf60-c13102f85e19'	System	21 Sep 2020 20:10:37
User entered 'No (N)'	System	21 Sep 2020 20:10:37

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-21T16:10:34', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '4dc81063-44bf-4e5e-bf60-c13102f85e19'	System	21 Sep 2020 20:10:37
User entered '21 Sep 2020 16:10'	System	21 Sep 2020 20:10:37

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	18 Sep 2020 19:40:35
User entered 'Day 5'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-23T05:59:25', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'cfcf4ca3-af3f-4df3-bdf8-b1b5a8308914' User entered 'None (0)'	System	23 Sep 2020 09:59:49
	System	23 Sep 2020 09:59:49

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-23T05:59:28', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'cfcf4ca3-af3f-4df3-bdf8-b1b5a8308914' User entered 'None (0)'	System	23 Sep 2020 09:59:49
	System	23 Sep 2020 09:59:49

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-23T05:59:30', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'cfcf4ca3-af3f-4df3-bdf8-b1b5a8308914' User entered 'None (0)'	System	23 Sep 2020 09:59:49
	System	23 Sep 2020 09:59:49

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-23T05:59:32', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'cfcf4ca3-af3f-4df3-bdf8-b1b5a8308914' User entered 'None (0)'	System	23 Sep 2020 09:59:49
	System	23 Sep 2020 09:59:49

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-23T05:59:35', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'cfcf4ca3-af3f-4df3-bdf8-b1b5a8308914' User entered 'None (0)'	System	23 Sep 2020 09:59:49
	System	23 Sep 2020 09:59:49

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-23T05:59:38', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'cfcf4ca3-af3f-4df3-bdf8-b1b5a8308914' User entered 'None (0)'	System	23 Sep 2020 09:59:49
	System	23 Sep 2020 09:59:49

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-23T05:59:43', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'cfcf4ca3-af3f-4df3-bdf8-b1b5a8308914' User entered 'No (N)'	System	23 Sep 2020 09:59:49
	System	23 Sep 2020 09:59:49

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-23T05:59:46', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'cfcf4ca3-af3f-4df3-bdf8-b1b5a8308914' User entered '23 Sep 2020 05:59'	System	23 Sep 2020 09:59:49
	System	23 Sep 2020 09:59:49

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	18 Sep 2020 19:40:35
User entered 'Day 6'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-23T20:40:00', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'bf6f07b6-ce6b-4f5d-91a6-11c0f63a0b3e' User entered 'None (0)'	System	24 Sep 2020 00:40:23
	System	24 Sep 2020 00:40:23

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-23T20:40:02', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'bf6f07b6-ce6b-4f5d-91a6-11c0f63a0b3e' User entered 'None (0)'	System	24 Sep 2020 00:40:23
	System	24 Sep 2020 00:40:23

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-23T20:40:04', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'bf6f07b6-ce6b-4f5d-91a6-11c0f63a0b3e' User entered 'None (0)'	System	24 Sep 2020 00:40:23
	System	24 Sep 2020 00:40:23

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-23T20:40:06', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'bf6f07b6-ce6b-4f5d-91a6-11c0f63a0b3e' User entered 'None (0)'	System	24 Sep 2020 00:40:23
	System	24 Sep 2020 00:40:23

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-23T20:40:08', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'bf6f07b6-ce6b-4f5d-91a6-11c0f63a0b3e' User entered 'None (0)'	System	24 Sep 2020 00:40:23
	System	24 Sep 2020 00:40:23

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-23T20:40:10', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'bf6f07b6-ce6b-4f5d-91a6-11c0f63a0b3e' User entered 'None (0)'	System	24 Sep 2020 00:40:23
	System	24 Sep 2020 00:40:23

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-23T20:40:18', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'bf6f07b6-ce6b-4f5d-91a6-11c0f63a0b3e' User entered 'No (N)'	System	24 Sep 2020 00:40:23
	System	24 Sep 2020 00:40:23

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-23T20:40:21', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'bf6f07b6-ce6b-4f5d-91a6-11c0f63a0b3e' User entered '23 Sep 2020 20:40'	System	24 Sep 2020 00:40:23
	System	24 Sep 2020 00:40:23

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	18 Sep 2020 19:40:35
User entered 'Day 7'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-25T03:00:28', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'efc694be-83ad-4a8a-8b91-08b7dec75e4b' User entered 'None (0)'	System	25 Sep 2020 07:00:53
	System	25 Sep 2020 07:00:53

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-25T03:00:30', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'efc694be-83ad-4a8a-8b91-08b7dec75e4b' User entered 'None (0)'	System	25 Sep 2020 07:00:53
	System	25 Sep 2020 07:00:53

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-25T03:00:33', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'efc694be-83ad-4a8a-8b91-08b7dec75e4b' User entered 'None (0)'	System	25 Sep 2020 07:00:53
	System	25 Sep 2020 07:00:53

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-25T03:00:35', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'efc694be-83ad-4a8a-8b91-08b7dec75e4b' User entered 'None (0)'	System	25 Sep 2020 07:00:53
	System	25 Sep 2020 07:00:53

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-25T03:00:37', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'efc694be-83ad-4a8a-8b91-08b7dec75e4b' User entered 'None (0)'	System	25 Sep 2020 07:00:53
	System	25 Sep 2020 07:00:53

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-25T03:00:41', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'efc694be-83ad-4a8a-8b91-08b7dec75e4b' User entered 'None (0)'	System	25 Sep 2020 07:00:53
	System	25 Sep 2020 07:00:53

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:54

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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-25T03:00:46', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'efc694be-83ad-4a8a-8b91-08b7dec75e4b' User entered 'No (N)'	System	25 Sep 2020 07:00:53
	System	25 Sep 2020 07:00:53

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-09-25T03:00:49', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'efc694be-83ad-4a8a-8b91-08b7dec75e4b' User entered '25 Sep 2020 03:00'	System	25 Sep 2020 07:00:53
	System	25 Sep 2020 07:00:53

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 19:40:35

US3672199

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:22:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 19:40:35

US3672199

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 16:53:23

US3672199

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '25 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 16:53:23

US3672199

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	29 Sep 2020 16:53:23

US3672199

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 16:53:23

US3672199

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 16:53:28

US3672199

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered 'I'	System	29 Sep 2020 16:53:28

US3672199

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 20:25:12

US3672199

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '5 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 20:25:12

US3672199

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 20:25:12

US3672199

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 20:25:12

US3672199

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 20:25:16

US3672199

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered 'I'	System	05 Oct 2020 20:25:16

US3672199

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 16:56:52

US3672199

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '12 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 16:56:52

US3672199

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Oct 2020 16:56:52

US3672199

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 16:56:52

US3672199

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 16:57:02

US3672199

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered 'I'	System	12 Oct 2020 16:57:02

US3672199

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:46:49
User closed query 'Per CDM: Data is required. Please enter a response and complete form as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 14:53:12
User signature succeeded.	Cynthia Strout (b) (4)	23 Apr 2021 14:31:34
Query 'Per CDM: Data is required. Please enter a response and complete form as appropriate. ' answered with 'Updated per source' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 14:06:15
Signature has been broken.	(b) (4), (b) (6)	23 Apr 2021 14:06:07
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 14:06:07
User opened query 'Per CDM: Data is required. Please enter a response and complete form as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 22:16:38
Data hard unlocked.	(b) (4), (b) (6)	22 Apr 2021 21:09:24
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	28 Oct 2020 11:05:09
Query 'Data is required. Please complete.' answered with 'DATA ENTERED IN ERROR THEN REMOVED' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 19:14:32
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 17:49:16
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 17:49:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 17:32:07

US3672199

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:54

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:46:49
User signature succeeded.	Cynthia Strout (b) (4)	23 Apr 2021 14:31:34
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 14:06:07
User entered '14 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 14:06:07
Data hard unlocked.	(b) (4), (b) (6)	22 Apr 2021 21:09:24
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
	(b) (4)	
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	12 Oct 2020 17:49:16
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered by data change (Site from System).	System	12 Oct 2020 17:49:16
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 17:49:16
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	12 Oct 2020 17:32:07
User entered '12 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 17:32:07

US3672199

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:54

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 02:46:49
User signature succeeded.	Cynthia Strout (b) (4)	23 Apr 2021 14:31:34
Signature has been broken.	(b) (4)	23 Apr 2021 14:06:07
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 14:06:07
Data hard unlocked.	(b) (4), (b) (6)	22 Apr 2021 21:09:24
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 17:49:16
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	12 Oct 2020 17:32:07

US3672199

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:46:49
User entered 'VISIT3'	System	23 Apr 2021 14:06:07
Data hard unlocked.	(b) (4), (b) (6)	22 Apr 2021 21:09:24
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered empty.	System	12 Oct 2020 17:49:16
User entered 'VISIT3'	System	12 Oct 2020 17:32:07

US3672199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Oct 2020 14:40:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Oct 2020 14:40:39
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 14:40:39
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 17:49:42
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 17:49:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 17:32:41

US3672199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 17:49:42
User entered '12 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 17:32:41

US3672199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 17:49:42
User entered '13:07'	(b) (4), (b) (6)	12 Oct 2020 17:32:41

US3672199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered empty.	System	12 Oct 2020 17:49:42
User entered '12 Oct 2020 13:07'	System	12 Oct 2020 17:32:41

US3672199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 17:49:42
User entered '98.1' F	(b) (4), (b) (6)	12 Oct 2020 17:32:41

US3672199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 17:49:42
User entered 'Oral (Oral)'	(b) (4), (b) (6)	12 Oct 2020 17:32:41

US3672199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 17:32:41

US3672199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 17:49:42
User entered '70'	(b) (4), (b) (6)	12 Oct 2020 17:32:41

US3672199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered empty.	System	12 Oct 2020 17:49:42
User entered 'bpm'	System	12 Oct 2020 17:32:41

US3672199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 17:49:42
User entered '16'	(b) (4), (b) (6)	12 Oct 2020 17:32:41

US3672199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered empty.	System	12 Oct 2020 17:49:42
User entered 'breaths/min'	System	12 Oct 2020 17:32:41

US3672199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 17:49:42
User entered '110'	(b) (4), (b) (6)	12 Oct 2020 17:32:41

US3672199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered empty.	System	12 Oct 2020 17:49:42
User entered 'mmHg'	System	12 Oct 2020 17:32:41

US3672199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 17:49:42
User entered '65'	(b) (4), (b) (6)	12 Oct 2020 17:32:41

US3672199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered empty.	System	12 Oct 2020 17:49:42
User entered 'mmHg'	System	12 Oct 2020 17:32:41

US3672199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35

US3672199

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35

US3672199

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:54

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	27 Oct 2020 21:10:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Oct 2020 21:10:39
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 21:10:39
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 17:49:48
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 17:49:48
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 17:32:51

US3672199

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 17:32:51

US3672199

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Oct 2020 17:48:21
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 17:48:21
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 17:50:03
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 17:50:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 17:33:11

US3672199

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '14 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 17:48:21
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 17:50:03
User entered '12 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 17:33:11

US3672199

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:54

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User entered '13:26' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 17:48:21
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 17:50:03
User entered '13:18'	(b) (4), (b) (6)	12 Oct 2020 17:33:11

US3672199

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered '14 Oct 2020 13:26'	System	14 Oct 2020 17:48:21
User entered empty.	System	12 Oct 2020 17:50:03
User entered '12 Oct 2020 13:18'	System	12 Oct 2020 17:33:11

US3672199

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:02:49
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Oct 2020 17:48:26
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 17:48:26
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Oct 2020 17:50:08
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Oct 2020 17:50:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 17:33:17

US3672199

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered '1'	System	14 Oct 2020 17:48:26
User entered empty.	System	12 Oct 2020 17:50:08
User entered '1'	System	12 Oct 2020 17:33:17

US3672199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	19 Aug 2020 19:03:13
User entered 'Day 64'	System	19 Aug 2020 19:03:13

US3672199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-10-22T18:02:15', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '7c5236c8-d5c9-44da-8e5e-8e14fcc2a780'	System	22 Oct 2020 22:02:37
User entered 'No (N)'	System	22 Oct 2020 22:02:37

US3672199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Have you been exposed to someone with 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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-10-22T18:02:24', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '7c5236c8-d5c9-44da-8e5e-8e14fcc2a780'	System	22 Oct 2020 22:02:37
User entered 'No (N)'	System	22 Oct 2020 22:02:37

US3672199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-10-22T18:02:31', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '7c5236c8-d5c9-44da-8e5e-8e14fcc2a780' User entered '22 Oct 2020 18:02:31'	System	22 Oct 2020 22:02:37
	System	22 Oct 2020 22:02:37

US3672199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	19 Aug 2020 19:03:13
User entered '19 Oct 2020 00:01'	System	19 Aug 2020 19:03:13

US3672199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	19 Aug 2020 19:03:13
User entered '23 Oct 2020 23:59'	System	19 Aug 2020 19:03:13

US3672199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	19 Aug 2020 19:03:13
User entered 'Day 71'	System	19 Aug 2020 19:03:13

US3672199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-10-26T00:01:52', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '256ce336-29dd-4c07-84af-a0eeebec2ec6'	System	26 Oct 2020 04:02:09
User entered 'No (N)'	System	26 Oct 2020 04:02:09

US3672199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Have you been exposed to someone with 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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-10-26T00:02:00', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '256ce336-29dd-4c07-84af-a0eeebec6'	System	26 Oct 2020 04:02:09
User entered 'No (N)'	System	26 Oct 2020 04:02:09

US3672199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-10-26T00:02:06', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '256ce336-29dd-4c07-84af-a0eeebec6'	System	26 Oct 2020 04:02:09
User entered '26 Oct 2020 00:02:06'	System	26 Oct 2020 04:02:09

US3672199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	19 Aug 2020 19:03:13
User entered '26 Oct 2020 00:01'	System	19 Aug 2020 19:03:13

US3672199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	19 Aug 2020 19:03:13
User entered '30 Oct 2020 23:59'	System	19 Aug 2020 19:03:13

US3672199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	19 Aug 2020 19:03:13
User entered 'Day 78'	System	19 Aug 2020 19:03:13

US3672199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-11-04T12:00:47', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '44219e59-876f-4fe0-89ca-f04f76a2921b' User entered 'No (N)'	System	04 Nov 2020 17:02:49
	System	04 Nov 2020 17:02:49

US3672199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Have you been exposed to someone with 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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-11-04T12:00:52', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '44219e59-876f-4fe0-89ca-f04f76a2921b'	System	04 Nov 2020 17:02:49
User entered 'No (N)'	System	04 Nov 2020 17:02:49

US3672199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-11-04T12:00:55', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '44219e59-876f-4fe0-89ca-f04f76a2921b' User entered '04 Nov 2020 12:00:55'	System	04 Nov 2020 17:02:49
	System	04 Nov 2020 17:02:49

US3672199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	19 Aug 2020 19:03:13
User entered '02 Nov 2020 00:01'	System	19 Aug 2020 19:03:13

US3672199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	19 Aug 2020 19:03:13
User entered '06 Nov 2020 23:59'	System	19 Aug 2020 19:03:13

US3672199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	19 Aug 2020 19:03:13
User entered 'Day 92'	System	19 Aug 2020 19:03:13

US3672199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-11-18T12:00:46', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '54d6022a-b97f-4b1d-9893-89834de817e6' User entered 'No (N)'	System	18 Nov 2020 17:01:15
	System	18 Nov 2020 17:01:15

US3672199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Have you been exposed to someone with 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 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-11-18T12:00:51', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '54d6022a-b97f-4b1d-9893-89834de817e6' User entered 'No (N)'	System	18 Nov 2020 17:01:15
	System	18 Nov 2020 17:01:15

US3672199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-11-18T12:00:55', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '54d6022a-b97f-4b1d-9893-89834de817e6' User entered '18 Nov 2020 12:00:55'	System	18 Nov 2020 17:01:15
	System	18 Nov 2020 17:01:15

US3672199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	19 Aug 2020 19:03:13
User entered '16 Nov 2020 00:01'	System	19 Aug 2020 19:03:13

US3672199

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:15:17
Data entry locked.	System	19 Aug 2020 19:03:13
User entered '20 Nov 2020 23:59'	System	19 Aug 2020 19:03:13

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-11-23T00:02:37', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'a76b0109-9235-4288-a10f-7182b0727753'	System	23 Nov 2020 05:02:51
User entered 'No (N)'	System	23 Nov 2020 05:02:51

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

Have you been exposed to someone with 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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-11-23T00:02:43', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'a76b0109-9235-4288-a10f-7182b0727753'	System	23 Nov 2020 05:02:51
User entered 'No (N)'	System	23 Nov 2020 05:02:51

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-11-23T00:02:47', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'a76b0109-9235-4288-a10f-7182b0727753' User entered '23 Nov 2020 00:02:47'	System	23 Nov 2020 05:02:51
	System	23 Nov 2020 05:02:51

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-11-30T18:02:16', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '1f06621d-34e1-40d1-adf5-50752e1bbfe3' User entered 'No (N)'	System	30 Nov 2020 23:02:30
	System	30 Nov 2020 23:02:30

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

Have you been exposed to someone with 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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-11-30T18:02:21', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '1f06621d-34e1-40d1-adf5-50752e1bbfe3' User entered 'No (N)'	System	30 Nov 2020 23:02:30

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-11-30T18:02:24', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '1f06621d-34e1-40d1-adf5-50752e1bbfe3' User entered '30 Nov 2020 18:02:24'	System	30 Nov 2020 23:02:30
	System	30 Nov 2020 23:02:30

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-12-08T13:58:54', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'c064cb3d-a323-491a-9bd2-a894e187cfaa' User entered 'No (N)'	System	08 Dec 2020 18:59:07
	System	08 Dec 2020 18:59:07

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

Have you been exposed to someone with 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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-12-08T13:59:00', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'c064cb3d-a323-491a-9bd2-a894e187cfaa' User entered 'No (N)'	System	08 Dec 2020 18:59:07
	System	08 Dec 2020 18:59:07

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-12-08T13:59:03', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'c064cb3d-a323-491a-9bd2-a894e187cfaa' User entered '08 Dec 2020 13:59:03'	System	08 Dec 2020 18:59:07
	System	08 Dec 2020 18:59:07

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-12-13T12:04:44', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '44a7bf1f-6681-4f93-8724-1dc9f97f970d' User entered 'No (N)'	System	13 Dec 2020 17:04:58
	System	13 Dec 2020 17:04:58

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

Have you been exposed to someone with 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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-12-13T12:04:49', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '44a7bf1f-6681-4f93-8724-1dc9f97f970d' User entered 'No (N)'	System	13 Dec 2020 17:04:58
	System	13 Dec 2020 17:04:58

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-12-13T12:04:53', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '44a7bf1f-6681-4f93-8724-1dc9f97f970d' User entered '13 Dec 2020 12:04:53'	System	13 Dec 2020 17:04:58
	System	13 Dec 2020 17:04:58

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-12-20T12:00:55', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '4f66dd82-8bb6-489a-84bd-ed8eaea11288' User entered 'No (N)'	System	20 Dec 2020 17:01:10
	System	20 Dec 2020 17:01:10

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

Have you been exposed to someone with 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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-12-20T12:01:00', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '4f66dd82-8bb6-489a-84bd-ed8eaea11288'	System	20 Dec 2020 17:01:10
User entered 'No (N)'	System	20 Dec 2020 17:01:10

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2020-12-20T12:01:04', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '4f66dd82-8bb6-489a-84bd-ed8eaea11288' User entered '20 Dec 2020 12:01:04'	System	20 Dec 2020 17:01:10
	System	20 Dec 2020 17:01:10

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-01-03T12:09:47', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '6247a13f-9c8d-4400-abbb-48910c38a34c' User entered 'Yes (Y)'	System	03 Jan 2021 17:10:44
	System	03 Jan 2021 17:10:44

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Have you been exposed to someone with 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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-01-03T12:09:52', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '6247a13f-9c8d-4400-abbb-48910c38a34c' User entered 'No (N)'	System	03 Jan 2021 17:10:44
	System	03 Jan 2021 17:10:44

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-01-03T12:09:57', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '6247a13f-9c8d-4400-abbb-48910c38a34c' User entered 'No (N)'	System	03 Jan 2021 17:10:44
	System	03 Jan 2021 17:10:44

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-01-03T12:10:15', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '6247a13f-9c8d-4400-abbb-48910c38a34c' User entered 'Yes (Y)'	System	03 Jan 2021 17:10:44
	System	03 Jan 2021 17:10:44

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-01-03T12:10:29', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '6247a13f-9c8d-4400-abbb-48910c38a34c'	System	03 Jan 2021 17:10:44
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 Jan 2021 17:10:44

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-01-03T12:10:34', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '6247a13f-9c8d-4400-abb-48910c38a34c' User entered '03 Jan 2021 12:10:34'	System	03 Jan 2021 17:10:44
	System	03 Jan 2021 17:10:44

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-01-08T01:18:13', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '60ee00fd-1dfd-42f5-9235-3fa2518805fa' User entered 'No (N)'	System	08 Jan 2021 06:18:24
	System	08 Jan 2021 06:18:24

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

Have you been exposed to someone with 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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-01-08T01:18:18', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '60ee00fd-1dfd-42f5-9235-3fa2518805fa' User entered 'No (N)'	System	08 Jan 2021 06:18:24

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-01-08T01:18:22', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '60ee00fd-1dfd-42f5-9235-3fa2518805fa' User entered '08 Jan 2021 01:18:22'	System	08 Jan 2021 06:18:24
	System	08 Jan 2021 06:18:24

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-01-18T20:33:56', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '7fbcd193-1637-43d2-9b74-8ffaa24b003d' User entered 'No (N)'	System	19 Jan 2021 01:34:07
	System	19 Jan 2021 01:34:07

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

Have you been exposed to someone with 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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-01-18T20:34:01', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '7fbcd193-1637-43d2-9b74-8ffaa24b003d' User entered 'No (N)'	System	19 Jan 2021 01:34:07

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-01-18T20:34:04', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '7fbcd193-1637-43d2-9b74-8ffaa24b003d' User entered '18 Jan 2021 20:34:04'	System	19 Jan 2021 01:34:07

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-01-22T06:01:39', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '1317bc4e-d283-4ad7-8f02-943ba3f637ba' User entered 'No (N)'	System	22 Jan 2021 11:01:52

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Have you been exposed to someone with 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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-01-22T06:01:45', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '1317bc4e-d283-4ad7-8f02-943ba3f637ba' User entered 'No (N)'	System	22 Jan 2021 11:01:52
	System	22 Jan 2021 11:01:52

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-01-22T06:01:49', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '1317bc4e-d283-4ad7-8f02-943ba3f637ba' User entered '22 Jan 2021 06:01:49'	System	22 Jan 2021 11:01:52
	System	22 Jan 2021 11:01:52

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-01-29T07:36:29', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'fa8676a6-642d-4bc4-a335-a1f90726f3a0'	System	29 Jan 2021 12:36:42
User entered 'No (N)'	System	29 Jan 2021 12:36:42

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

Have you been exposed to someone with 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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-01-29T07:36:34', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'fa8676a6-642d-4bc4-a335-a1f90726f3a0'	System	29 Jan 2021 12:36:42
User entered 'No (N)'	System	29 Jan 2021 12:36:42

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-01-29T07:36:38', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'fa8676a6-642d-4bc4-a335-a1f90726f3a0' User entered '29 Jan 2021 07:36:38'	System	29 Jan 2021 12:36:42

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-02-06T08:50:07', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'f69453c9-8a99-458e-b46c-cb9f0c89be7c'	System	06 Feb 2021 13:50:18
User entered 'No (N)'	System	06 Feb 2021 13:50:18

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

Have you been exposed to someone with 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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-02-06T08:50:12', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'f69453c9-8a99-458e-b46c-cb9f0c89be7c'	System	06 Feb 2021 13:50:18
User entered 'No (N)'	System	06 Feb 2021 13:50:18

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-02-06T08:50:15', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'f69453c9-8a99-458e-b46c-cb9f0c89be7c' User entered '06 Feb 2021 08:50:15'	System	06 Feb 2021 13:50:18
	System	06 Feb 2021 13:50:18

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-02-15T18:07:36', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '13fca568-433f-4081-86c6-77d57a395e69'	System	15 Feb 2021 23:12:55
User entered 'No (N)'	System	15 Feb 2021 23:12:55

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

Have you been exposed to someone with 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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-02-15T18:07:40', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '13fca568-433f-4081-86c6-77d57a395e69'	System	15 Feb 2021 23:12:55
User entered 'No (N)'	System	15 Feb 2021 23:12:55

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-02-15T18:07:44', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '13fca568-433f-4081-86c6-77d57a395e69'	System	15 Feb 2021 23:12:55
User entered '15 Feb 2021 18:07:44'	System	15 Feb 2021 23:12:55

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-02-19T13:34:44', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '5eac996b-2ca5-455c-9926-7e58594b8db0' User entered 'No (N)'	System	19 Feb 2021 18:34:56
	System	19 Feb 2021 18:34:56

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

Have you been exposed to someone with 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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-02-19T13:34:49', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '5eac996b-2ca5-455c-9926-7e58594b8db0' User entered 'No (N)'	System	19 Feb 2021 18:34:56

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-02-19T13:34:53', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '5eac996b-2ca5-455c-9926-7e58594b8db0' User entered '19 Feb 2021 13:34:53'	System	19 Feb 2021 18:34:56

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-02-26T02:28:19', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '866404e0-b28a-403a-9680-2af8e71b2481' User entered 'No (N)'	System	26 Feb 2021 08:07:10
	System	26 Feb 2021 08:07:10

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

Have you been exposed to someone with 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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-02-26T02:28:22', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '866404e0-b28a-403a-9680-2af8e71b2481' User entered 'No (N)'	System	26 Feb 2021 08:07:10
	System	26 Feb 2021 08:07:10

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-02-26T02:28:26', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '866404e0-b28a-403a-9680-2af8e71b2481' User entered '26 Feb 2021 02:28:26'	System	26 Feb 2021 08:07:10
	System	26 Feb 2021 08:07:10

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-03-05T08:25:50', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '664b1ff5-f1cd-423e-8d6f-8647bb41072d'	System	05 Mar 2021 13:26:09
User entered 'No (N)'	System	05 Mar 2021 13:26:09

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Have you been exposed to someone with 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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-03-05T08:25:56', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '664b1ff5-f1cd-423e-8d6f-8647bb41072d'	System	05 Mar 2021 13:26:09
User entered 'No (N)'	System	05 Mar 2021 13:26:09

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-03-05T08:26:04', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '664b1ff5-f1cd-423e-8d6f-8647bb41072d' User entered '05 Mar 2021 08:26:04'	System	05 Mar 2021 13:26:09
	System	05 Mar 2021 13:26:09

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-03-12T12:18:55', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'c50943b0-d871-460e-95f8-c8a5e6e2f68e' User entered 'No (N)'	System	12 Mar 2021 17:19:08
	System	12 Mar 2021 17:19:08

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

Have you been exposed to someone with 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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-03-12T12:19:00', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'c50943b0-d871-460e-95f8-c8a5e6e2f68e' User entered 'No (N)'	System	12 Mar 2021 17:19:08

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-03-12T12:19:03', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'c50943b0-d871-460e-95f8-c8a5e6e2f68e' User entered '12 Mar 2021 12:19:03'	System	12 Mar 2021 17:19:08
	System	12 Mar 2021 17:19:08

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-03-19T05:27:25-04:00', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '1bebe4ce-936e-4687-b03e-d913f3d3e36b'	System	19 Mar 2021 09:27:37
User entered 'No (N)'	System	19 Mar 2021 09:27:37

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

Have you been exposed to someone with 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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-03-19T05:27:30-04:00', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '1bebe4ce-936e-4687-b03e-d913f3d3e36b'	System	19 Mar 2021 09:27:37
User entered 'No (N)'	System	19 Mar 2021 09:27:37

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-03-19T05:27:34-04:00', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '1bebe4ce-936e-4687-b03e-d913f3d3e36b' User entered '19 Mar 2021 05:27:34'	System	19 Mar 2021 09:27:37
	System	19 Mar 2021 09:27:37

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-03-28T12:55:28-04:00', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '766e1893-6702-4276-84f2-b8a7422576ad'	System	28 Mar 2021 16:55:39
User entered 'No (N)'	System	28 Mar 2021 16:55:39

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

Have you been exposed to someone with 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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-03-28T12:55:32-04:00', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '766e1893-6702-4276-84f2-b8a7422576ad'	System	28 Mar 2021 16:55:39
User entered 'No (N)'	System	28 Mar 2021 16:55:39

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-03-28T12:55:36-04:00', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '766e1893-6702-4276-84f2-b8a7422576ad' User entered '28 Mar 2021 12:55:36'	System	28 Mar 2021 16:55:39
	System	28 Mar 2021 16:55:39

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-04-02T08:25:10-04:00', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'e64a6fb3-0214-4eb5-9ff7-4d347bdcbe23'	System	02 Apr 2021 12:25:25
User entered 'No (N)'	System	02 Apr 2021 12:25:25

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

Have you been exposed to someone with 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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-04-02T08:25:15-04:00', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'e64a6fb3-0214-4eb5-9ff7-4d347bdcbe23'	System	02 Apr 2021 12:25:25
User entered 'No (N)'	System	02 Apr 2021 12:25:25

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-04-02T08:25:22-04:00', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: 'e64a6fb3-0214-4eb5-9ff7-4d347bdcbe23'	System	02 Apr 2021 12:25:25
User entered '02 Apr 2021 08:25:22'	System	02 Apr 2021 12:25:25

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-04-09T03:42:41-04:00', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '62aa71ea-1c78-4744-811b-a1107690617f' User entered 'No (N)'	System	09 Apr 2021 07:42:52
	System	09 Apr 2021 07:42:52

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Have you been exposed to someone with 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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-04-09T03:42:45-04:00', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '62aa71ea-1c78-4744-811b-a1107690617f' User entered 'No (N)'	System	09 Apr 2021 07:42:52
	System	09 Apr 2021 07:42:52

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-04-09T03:42:49-04:00', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '62aa71ea-1c78-4744-811b-a1107690617f' User entered '09 Apr 2021 03:42:49'	System	09 Apr 2021 07:42:52
	System	09 Apr 2021 07:42:52

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-04-18T13:33:38-04:00', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '8f01eac1-2198-4ff0-90de-e15014c6967f' User entered 'No (N)'	System	26 Apr 2021 22:14:34
	System	26 Apr 2021 22:14:34

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Have you been exposed to someone with 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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-04-18T13:33:43-04:00', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '8f01eac1-2198-4ff0-90de-e15014c6967f' User entered 'No (N)'	System	26 Apr 2021 22:14:34
	System	26 Apr 2021 22:14:34

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-04-18T13:33:46-04:00', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '8f01eac1-2198-4ff0-90de-e15014c6967f' User entered '18 Apr 2021 13:33:46'	System	26 Apr 2021 22:14:34
	System	26 Apr 2021 22:14:34

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-04-26T18:12:39-04:00', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '9fa307a1-cbdb-47e9-b2e7-59f54a3a884c' User entered 'No (N)'	System	26 Apr 2021 22:14:44
	System	26 Apr 2021 22:14:44

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

Have you been exposed to someone with 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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-04-26T18:12:44-04:00', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '9fa307a1-cbdb-47e9-b2e7-59f54a3a884c'	System	26 Apr 2021 22:14:44
User entered 'No (N)'	System	26 Apr 2021 22:14:44

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-04-26T18:12:47-04:00', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '9fa307a1-cbdb-47e9-b2e7-59f54a3a884c' User entered '26 Apr 2021 18:12:47'	System	26 Apr 2021 22:14:44
	System	26 Apr 2021 22:14:44

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-05-02T12:37:57-04:00', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '50535f54-3b98-4c3e-bb09-3c881ce2c273'	System	02 May 2021 16:38:08
User entered 'No (N)'	System	02 May 2021 16:38:08

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Have you been exposed to someone with 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 (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-05-02T12:38:01-04:00', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '50535f54-3b98-4c3e-bb09-3c881ce2c273'	System	02 May 2021 16:38:08
User entered 'No (N)'	System	02 May 2021 16:38:08

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-05-02T12:38:05-04:00', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '50535f54-3b98-4c3e-bb09-3c881ce2c273'	System	02 May 2021 16:38:08
User entered '02 May 2021 12:38:05'	System	02 May 2021 16:38:08

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 23:09:45

US3672199

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:22:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:09:45
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 23:09:45

US3672199

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:22:54

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:24:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-03-01T08:20:30', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '7f7354e0-8422-4f2d-8798-3ade5a4748c8' User entered 'No (N)'	System	01 Mar 2021 13:20:39
	System	01 Mar 2021 13:20:39

US3672199

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:22:54

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:24:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4E0DF3A-16FB-4D6A-B2C3-DB7FC4608CAD)', Time: '2021-03-01T08:20:35', User OID: 'PatientReportedOutcome (US3672199)', ODM File OID: '7f7354e0-8422-4f2d-8798-3ade5a4748c8' User entered '01 Mar 2021 08:20:35'	System	01 Mar 2021 13:20:39
	System	01 Mar 2021 13:20:39

US3672199

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:51:21

US3672199

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '13 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:51:21

US3672199

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:51:21

US3672199

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:51:21

US3672199

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 16:51:36

US3672199

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:03:35
User entered 'I'	System	13 Nov 2020 16:51:36

US3672199

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:11:17
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:58:35

US3672199

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:11:17
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '3 Dec 2020'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:58:35

US3672199

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:11:17
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:58:35

US3672199

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:11:17
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:58:35

US3672199

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:11:17
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 20:58:46

US3672199

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:11:17
User entered 'I'	System	03 Dec 2020 20:58:46

US3672199

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:11:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Feb 2021 21:51:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Feb 2021 21:49:15

US3672199

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:11:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Feb 2021 21:51:38
User entered '19 Jan 2021'	(b) (4), (b) (6)	16 Feb 2021 21:49:15

US3672199

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:11:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	16 Feb 2021 21:51:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Feb 2021 21:49:15

US3672199

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:11:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:49:15

US3672199

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:11:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Feb 2021 21:49:21

US3672199

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:11:18
User entered 'I'	System	16 Feb 2021 21:49:21

US3672199

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:11:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Feb 2021 21:49:35

US3672199

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:11:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '16 Feb 2021'	(b) (4), (b) (6)	16 Feb 2021 21:49:35

US3672199

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:11:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Feb 2021 21:49:35

US3672199

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:11:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 21:49:35

US3672199

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:11:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Feb 2021 21:49:40

US3672199

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 23:11:18
User entered 'I'	System	16 Feb 2021 21:49:40

US3672199

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:30
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Mar 2021 17:16:06

US3672199

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:30
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:39
User entered '16 Mar 2021'	(b) (4), (b) (6)	16 Mar 2021 17:16:06

US3672199

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:30
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:39
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	16 Mar 2021 17:16:06

US3672199

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:30
User entered 'VISIT4'	System	16 Mar 2021 17:16:06

US3672199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:30
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:39
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	31 Mar 2021 19:38:12

US3672199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:30
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:39
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:38:12

US3672199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:30
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:39
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:38:12

US3672199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:30
User entered empty.	System	31 Mar 2021 19:38:12

US3672199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:30
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:39
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:38:12

US3672199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:30
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:39
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:38:12

US3672199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:30
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:39
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:38:12

US3672199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:30
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:39
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:38:12

US3672199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:30
User entered empty.	System	31 Mar 2021 19:38:12

US3672199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:30
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:39
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:38:12

US3672199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:30
User entered empty.	System	31 Mar 2021 19:38:12

US3672199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:30
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:39
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:38:12

US3672199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:30
User entered empty.	System	31 Mar 2021 19:38:12

US3672199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:30
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:39
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:38:12

US3672199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:30
User entered empty.	System	31 Mar 2021 19:38:12

US3672199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:30

US3672199

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:30

US3672199

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:30
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:39
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	16 Mar 2021 17:16:13

US3672199

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:30
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:39
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 17:16:13

US3672199

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:30
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Mar 2021 17:16:26

US3672199

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:30
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:39
User entered '16 Mar 2021'	(b) (4), (b) (6)	16 Mar 2021 17:16:26

US3672199

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:54

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:30
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:39
	(b) (4)	
User entered '09:15'	(b) (4), (b) (6)	16 Mar 2021 17:16:26

US3672199

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:30
User entered '16 Mar 2021 09:15'	System	16 Mar 2021 17:16:26

US3672199

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:30
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:39
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Mar 2021 17:16:36

US3672199

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:30
User entered 'I'	System	16 Mar 2021 17:16:36

US3672199

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:10:24

US3672199

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:39
User entered '13 Apr 2021'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:10:24

US3672199

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:10:24

US3672199

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:39
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:10:24

US3672199

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:10:33

US3672199

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:54

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Apr 2021 19:10:33

US3672199

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

Form: Visit Date

Generated On: 10 Jun 2021 09:22:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:01:51

US3672199

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

Form: Visit Date

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '19 Jan 2021'	(b) (4), (b) (6)	19 Jan 2021 18:01:51

US3672199

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

Form: Visit Date

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:01:51

US3672199

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

Form: Visit Date

Generated On: 10 Jun 2021 09:22:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User entered 'UNBLND_DECIDE'	System	19 Jan 2021 18:01:51

US3672199

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

Form: Unblinding

Generated On: 10 Jun 2021 09:22:54

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:14:17

US3672199

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

Form: Unblinding

Generated On: 10 Jun 2021 09:22:54

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:39
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:40:55
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:48:38

US3672199

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

Form: Unblinding

Generated On: 10 Jun 2021 09:22:54

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:14:17

US3672199

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

Form: Unblinding

Generated On: 10 Jun 2021 09:22:54

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:39
User closed query 'Per CDM, per sponsor review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 14:43:33
Query 'Per CDM, per sponsor review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 13:40:57
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	09 Apr 2021 13:40:55
User opened query 'Per CDM, per sponsor review: Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 08:37:20
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:48:38

US3672199

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

Form: Unblinding

Generated On: 10 Jun 2021 09:22:54

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '19 Jan 2021'	(b) (4), (b) (6)	19 Jan 2021 18:14:17

US3672199

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

Form: Unblinding

Generated On: 10 Jun 2021 09:22:54

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:14:17

US3672199

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

Form: Unblinding

Generated On: 10 Jun 2021 09:22:54

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 02:44:42
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	19 Jan 2021 18:14:17

US3672199

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

Form: Unblinding

Generated On: 10 Jun 2021 09:22:54

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 02:44:42
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	19 Jan 2021 18:14:17

US3672199

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

Form: Unblinding

Generated On: 10 Jun 2021 09:22:54

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Jan 2021 18:14:17

US3672199

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

Form: Unblinding

Generated On: 10 Jun 2021 09:22:54

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User entered '1'	System	19 Jan 2021 18:14:17

US3672199

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

Form: Unblinding

Generated On: 10 Jun 2021 09:22:54

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User entered 'I'	System	19 Jan 2021 18:14:17

US3672199

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:54

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered empty.	(b) (4), (b) (6)	19 Jan 2021 18:18:56

US3672199

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:54

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered empty.	(b) (4), (b) (6)	19 Jan 2021 18:18:56

US3672199

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:54

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User entered empty.	System	19 Jan 2021 18:18:56
DataPoint set to visible.	System	19 Jan 2021 18:14:17

US3672199

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:54

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered empty.	(b) (4), (b) (6)	19 Jan 2021 18:18:56

US3672199

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:54

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered empty.	(b) (4), (b) (6)	19 Jan 2021 18:18:56

US3672199

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:54

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User entered empty.	System	19 Jan 2021 18:18:56
DataPoint set to visible.	System	19 Jan 2021 18:14:17

US3672199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	19 Jan 2021 18:18:56

US3672199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:18:56

US3672199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '19 Jan 2021'	(b) (4), (b) (6)	19 Jan 2021 18:18:56

US3672199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '09:39'	(b) (4), (b) (6)	19 Jan 2021 18:18:56

US3672199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User entered '19 Jan 2021 09:39'	System	19 Jan 2021 18:18:56

US3672199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '98.5' F	(b) (4), (b) (6)	19 Jan 2021 18:18:56

US3672199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'Oral (Oral)'	(b) (4), (b) (6)	19 Jan 2021 18:18:56

US3672199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered empty.	(b) (4), (b) (6)	19 Jan 2021 18:18:56

US3672199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '65'	(b) (4), (b) (6)	19 Jan 2021 18:18:56

US3672199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User entered 'bpm'	System	19 Jan 2021 18:18:56

US3672199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '16'	(b) (4), (b) (6)	19 Jan 2021 18:18:56

US3672199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User entered 'breaths/min'	System	19 Jan 2021 18:18:56

US3672199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '150'	(b) (4), (b) (6)	19 Jan 2021 18:18:56

US3672199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User entered 'mmHg'	System	19 Jan 2021 18:18:56

US3672199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '66'	(b) (4), (b) (6)	19 Jan 2021 18:18:56

US3672199

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User entered 'mmHg'	System	19 Jan 2021 18:18:56

US3672199

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:54

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered empty.	(b) (4), (b) (6)	19 Jan 2021 18:18:56

US3672199

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:54

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered empty.	(b) (4), (b) (6)	19 Jan 2021 18:18:56

US3672199

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:22:54

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User entered empty.	System	19 Jan 2021 18:18:56
DataPoint set to visible.	System	19 Jan 2021 18:14:17

US3672199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	19 Jan 2021 18:18:56

US3672199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:18:56

US3672199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '19 Jan 2021'	(b) (4), (b) (6)	19 Jan 2021 18:18:56

US3672199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '10:35'	(b) (4), (b) (6)	19 Jan 2021 18:18:56

US3672199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User entered '19 Jan 2021 10:35'	System	19 Jan 2021 18:18:56

US3672199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '97.9' F	(b) (4), (b) (6)	19 Jan 2021 18:18:56

US3672199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:18:56

US3672199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered empty.	(b) (4), (b) (6)	19 Jan 2021 18:18:56

US3672199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '65'	(b) (4), (b) (6)	19 Jan 2021 18:18:56

US3672199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User entered 'bpm'	System	19 Jan 2021 18:18:56

US3672199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '12'	(b) (4), (b) (6)	19 Jan 2021 18:18:56

US3672199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User entered 'breaths/min'	System	19 Jan 2021 18:18:56

US3672199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '134'	(b) (4), (b) (6)	19 Jan 2021 18:18:56

US3672199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User entered 'mmHg'	System	19 Jan 2021 18:18:56

US3672199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '66'	(b) (4), (b) (6)	19 Jan 2021 18:18:56

US3672199

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User entered 'mmHg'	System	19 Jan 2021 18:18:56

US3672199

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:19:11

US3672199

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

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '19 Jan 2021'	(b) (4), (b) (6)	19 Jan 2021 18:19:11

US3672199

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

Form: Exposure

Generated On: 10 Jun 2021 09:22:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:19:40

US3672199

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

Form: Exposure

Generated On: 10 Jun 2021 09:22:54

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered empty.	(b) (4), (b) (6)	19 Jan 2021 18:19:40

US3672199

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

Form: Exposure

Generated On: 10 Jun 2021 09:22:54

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)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered empty.	(b) (4), (b) (6)	19 Jan 2021 18:19:40

US3672199

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

Form: Exposure

Generated On: 10 Jun 2021 09:22:54

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User entered 'mRNA-1273'	System	19 Jan 2021 18:19:40
DataPoint set to visible.	System	19 Jan 2021 18:14:17

US3672199

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

Form: Exposure

Generated On: 10 Jun 2021 09:22:54

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:19:40

US3672199

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

Form: Exposure

Generated On: 10 Jun 2021 09:22:54

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '10:04'	(b) (4), (b) (6)	19 Jan 2021 18:19:40

US3672199

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

Form: Exposure

Generated On: 10 Jun 2021 09:22:54

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User entered '19 Jan 2021 10:04'	System	19 Jan 2021 18:19:40

US3672199

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

Form: Exposure

Generated On: 10 Jun 2021 09:22:54

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:19:40

US3672199

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

Form: Exposure

Generated On: 10 Jun 2021 09:22:54

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User entered 'ONCE'	System	19 Jan 2021 18:19:40

US3672199

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

Form: Exposure

Generated On: 10 Jun 2021 09:22:54

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User entered 'INTRAMUSCULAR'	System	19 Jan 2021 18:19:40

US3672199

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:20:00

US3672199

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '19 Jan 2021'	(b) (4), (b) (6)	19 Jan 2021 18:20:00

US3672199

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:54

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '09:50'	(b) (4), (b) (6)	19 Jan 2021 18:20:00

US3672199

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:24
User entered '19 Jan 2021 09:50'	System	19 Jan 2021 18:20:00

US3672199

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:22:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:03
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:20:20

US3672199

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:03
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:20:20

US3672199

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:22:54

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:03
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '09:27'	(b) (4), (b) (6)	19 Jan 2021 18:20:20

US3672199

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:22:54

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:03
User entered '19 Jan 2021 09:27'	System	19 Jan 2021 18:20:20

US3672199

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

Form: Continuing

Generated On: 10 Jun 2021 09:22:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:03
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:20:25

US3672199

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

Form: Continuing

Generated On: 10 Jun 2021 09:22:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:09:03
User entered 'I'	System	19 Jan 2021 18:20:25

US3672199

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:28:03
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Jan 2021 18:36:46

US3672199

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:28:03
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:36:46

US3672199

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:28:03
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:36:46

US3672199

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:28:03
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 18:36:46

US3672199

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:28:03
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 18:36:49

US3672199

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:28:03
User entered 'I'	System	26 Jan 2021 18:36:49

US3672199

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:54

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:28:03
User entered '1'	System	26 Jan 2021 18:36:49
DataPoint set to visible.	System	26 Jan 2021 18:36:49

US3672199

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:00:42

US3672199

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '16 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:00:42

US3672199

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:00:42

US3672199

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User entered 'OLD29'	System	16 Feb 2021 15:00:42

US3672199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	16 Feb 2021 15:02:05

US3672199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:02:05

US3672199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '16 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:02:05

US3672199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '08:48'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:02:05

US3672199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User entered '16 Feb 2021 08:48'	System	16 Feb 2021 15:02:05

US3672199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:02:05

US3672199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:02:05

US3672199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:02:05

US3672199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '062'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:02:05

US3672199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User entered 'bpm'	System	16 Feb 2021 15:02:05

US3672199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '016'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:02:05

US3672199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User entered 'breaths/min'	System	16 Feb 2021 15:02:05

US3672199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '133'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:02:05

US3672199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User entered 'mmHg'	System	16 Feb 2021 15:02:05

US3672199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '065'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:02:05

US3672199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:22:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User entered 'mmHg'	System	16 Feb 2021 15:02:05

US3672199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	16 Feb 2021 15:02:05

US3672199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Feb 2021 15:02:11
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Feb 2021 15:02:11
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Feb 2021 15:02:05
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 15:02:05

US3672199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '16 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:02:05

US3672199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '09:22'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:02:05

US3672199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User entered '16 Feb 2021 09:22'	System	16 Feb 2021 15:02:05

US3672199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:02:05

US3672199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:02:05

US3672199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:02:05

US3672199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '056'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:02:05

US3672199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User entered 'bpm'	System	16 Feb 2021 15:02:05

US3672199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '016'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:02:05

US3672199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User entered 'breaths/min'	System	16 Feb 2021 15:02:05

US3672199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '128'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:02:05

US3672199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User entered 'mmHg'	System	16 Feb 2021 15:02:05

US3672199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '060'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:02:05

US3672199

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:22:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User entered 'mmHg'	System	16 Feb 2021 15:02:05

US3672199

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:02:20

US3672199

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '16 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:02:20

US3672199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:02:41

US3672199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:54

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:02:41

US3672199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 15:02:41

US3672199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:54

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User entered 'mRNA-1273'	System	16 Feb 2021 15:02:41
DataPoint set to visible.	System	26 Jan 2021 18:36:49

US3672199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:54

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '16 Feb 2021'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:02:41

US3672199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:54

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '08:51'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:02:41

US3672199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:54

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User entered '16 Feb 2021 08:51'	System	16 Feb 2021 15:02:41

US3672199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:54

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User closed query 'Per CDM: Response noted. Per protocol, the second dose should be administered in the same arm as the first dose Please consider to provide the reason to changing the arm. Thank you ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 11:00:46
Query 'Per CDM: Response noted. Per protocol, the second dose should be administered in the same arm as the first dose Please consider to provide the reason to changing the arm. Thank you ' answered with 'per PI' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 15:27:29
User opened query 'Per CDM: Response noted. Per protocol, the second dose should be administered in the same arm as the first dose Please consider to provide the reason to changing the arm. Thank you ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 10:54:17
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	(b) (4), (b) (6)	01 Mar 2021 10:51:47
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered with 'confirmed: first vaccine was in right, second in left. ' (Site from System).	Patty Howenstine (b) (4) (b) (4)	25 Feb 2021 14:50:41
Amendment Manager: User opened query 'Treatment System Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).		17 Feb 2021 01:14:00
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	16 Feb 2021 15:02:41

US3672199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:54

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User entered 'ONCE'	System	16 Feb 2021 15:02:41

US3672199

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:22:54

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User entered 'INTRAMUSCULAR'	System	16 Feb 2021 15:02:41

US3672199

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 15:02:46

US3672199

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:42
User entered 'I'	System	16 Feb 2021 15:02:46

US3672199

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:38:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 19:57:30

US3672199

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:38:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '25 Feb 2021'	(b) (4), (b) (6)	26 Feb 2021 19:57:30

US3672199

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:38:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	26 Feb 2021 19:57:30

US3672199

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:22:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:38:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered empty.	(b) (4), (b) (6)	26 Feb 2021 19:57:30

US3672199

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:38:21
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Feb 2021 19:57:35

US3672199

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:22:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:38:21
User entered 'I'	System	26 Feb 2021 19:57:35

US3672199

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:34:29
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Mar 2021 17:15:04

US3672199

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:34:29
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:39
User entered '16 Mar 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:15:04

US3672199

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:54

[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 05:34:29
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:39
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:15:04

US3672199

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:22:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:34:29
User entered 'OLD57'	System	16 Mar 2021 17:15:04

US3672199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:34:29
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:39
User closed query 'Visit 4 Day 209 and Visit OL-D57 are both dated 16Mar2021. However, the data on the Vital Signs in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile. Thank you' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 18:42:31
Query 'Visit 4 Day 209 and Visit OL-D57 are both dated 16Mar2021. However, the data on the Vital Signs in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile. Thank you' answered with 'Vitals signs match as vitals were both not assessed at both visits. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 19:29:03
User opened query 'Visit 4 Day 209 and Visit OL-D57 are both dated 16Mar2021. However, the data on the Vital Signs in these two visits do not match. If confirmed the visits occurred on the same day, the data must match. Please review and reconcile. Thank you' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 23:25:58
User entered 'No (N)'	(b) (4), (b) (6)	16 Mar 2021 17:15:32

US3672199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:34:29
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:39
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 17:15:32

US3672199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:34:29
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:39
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:15:32

US3672199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:34:29
User entered empty.	System	16 Mar 2021 17:15:32

US3672199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:34:29
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:39
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 17:15:32

US3672199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:34:29
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:39
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:15:32

US3672199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:34:29
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:39
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 17:15:32

US3672199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:34:29
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:39
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 17:15:32

US3672199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:34:29
User entered empty.	System	16 Mar 2021 17:15:32

US3672199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:34:29
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:39
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 17:15:32

US3672199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:34:29
User entered empty.	System	16 Mar 2021 17:15:32

US3672199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:34:29
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:39
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 17:15:32

US3672199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:34:29
User entered empty.	System	16 Mar 2021 17:15:32

US3672199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:34:29
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:39
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:15:32

US3672199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:34:29
User entered empty.	System	16 Mar 2021 17:15:32

US3672199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:34:29

US3672199

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:22:54

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:34:29

US3672199

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:34:29
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:15:36

US3672199

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:22:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:34:29
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:39
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 17:15:36

US3672199

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:34:29
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:15:52

US3672199

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:34:29
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:32
User entered '16 Mar 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:15:52

US3672199

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:54

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:34:29
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:10:32
User entered '09:15'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:15:52

US3672199

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:22:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:34:29
User entered '16 Mar 2021 09:15'	System	16 Mar 2021 17:15:52

US3672199

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:22:54

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:06:28
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:30:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 15:52:33

US3672199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:54

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:32:09
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:41:38
User entered	System	13 Oct 2020 13:41:33
'USA-US116-2020-mRNA-1273-P301000003'		
User entered 'New'	(b) (4), (b) (6)	13 Oct 2020 13:41:33

US3672199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:54

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:32:09
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Post procedural haematoma, LLT: Post procedural hematoma - version MedDRA\\23.0.	Coder Import (b) (4)	01 Nov 2020 19:51:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	01 Nov 2020 19:51:54
Data point term sent to Coder	System	27 Oct 2020 19:08:14
User closed query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	System	27 Oct 2020 19:07:25
Query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' answered with 'THERE IS ONLY ONE ADVERSE EVENT REPORTED. THE HEMATOMA R GROIN IS THE AE' (Site from System).	(b) (4), (b) (6)	27 Oct 2020 19:07:25
User opened query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	Coder Import (b) (4)	12 Oct 2020 23:23:17
Data point term sent to Coder	System	12 Oct 2020 17:19:15
User entered 'Hematoma R Groin following Angioplasty'	(b) (4), (b) (6)	12 Oct 2020 17:18:14

US3672199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:54

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:32:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 17:18:14

US3672199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:54

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:32:09
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 17:18:14

US3672199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:54

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:32:09
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 17:18:14

US3672199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:32:09
User entered '6 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 17:18:14

US3672199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:54

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:32:09
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 17:18:14

US3672199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:54

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 17:18:14

US3672199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:32:09
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 17:18:14

US3672199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:54

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:32:09
User entered '8 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 17:18:14

US3672199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:54

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:32:09
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 17:18:14

US3672199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:54

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Oct 2020 17:18:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:54

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:32:09
User closed query 'PV Query: Please reassess severity, as the subject was hospitalized please consider updating severity to grade 4.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 15:10:51
Query 'PV Query: Please reassess severity, as the subject was hospitalized please consider updating severity to grade 4.' answered with 'P.I considered it grade 3 since subject was hospitalized but not grade 4 due to event not being life threatening' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 15:31:55
User opened query 'PV Query: Please reassess severity, as the subject was hospitalized please consider updating severity to grade 4.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 14:45:18
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	12 Oct 2020 17:18:14

US3672199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:54

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:32:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 17:18:14

US3672199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:54

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:32:09
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 17:18:14

US3672199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:32:09
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 17:18:14

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Folder: Adverse Events

Form: Adverse Events (1)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:32:09
User entered 'I'	(b) (4), (b) (6)	12 Oct 2020 17:18:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:54

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:32:09
User entered '6 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 17:18:14

US3672199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:54

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:32:09
User entered '8 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 17:18:14

US3672199

Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:32:09
User entered 'No (N)'	(b) (4), (b) (6)	12 Oct 2020 17:18:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:54

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:32:09
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 17:18:14

US3672199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:32:09
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 17:18:14

US3672199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:32:09
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 17:18:14

US3672199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:32:09
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 17:18:14

US3672199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:54

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:32:09
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	12 Oct 2020 17:18:14

US3672199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:54

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:32:09
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	12 Oct 2020 17:18:14

US3672199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:54

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:03
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User closed query 'PV Query: As the second dose of study drug was given on 18 Sep 2020, please consider updating the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	12 Jan 2021 16:29:01
Query 'PV Query: As the second dose of study drug was given on 18 Sep 2020, please consider updating the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 20:09:44
DataPoint Un-verified.	(b) (4), (b) (6)	11 Jan 2021 20:09:39
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 20:09:39
User opened query 'PV Query: As the second dose of study drug was given on 18 Sep 2020, please consider updating the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 14:48:44
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:32:09
User closed query 'Per CDM: Per CCG pg.33, 'Not applicable' should be use if clinical event is prior to first dose/investigational product. Please consider to update appropriately or else, clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 04:24:51
Query 'Per CDM: Per CCG pg.33, 'Not applicable' should be use if clinical event is prior to first dose/investigational product. Please consider to update appropriately or else, clarify. Thank you. ' answered with 'action with IP updated' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 17:54:52
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Oct 2020 17:54:16
User opened query 'Per CDM: Per CCG pg.33, 'Not applicable' should be use if clinical event is prior to first dose/investigational product. Please consider to update appropriately or else, clarify. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 12:51:25

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:54

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	12 Oct 2020 17:18:14

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Folder: Adverse Events

Form: Adverse Events (1)

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Un-verified.	(b) (4), (b) (6)	17 Dec 2020 18:55:07
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 18:55:07
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:32:09
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 17:18:14

US3672199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:54

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:07
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User closed query 'Per DM CLR: RQ: Response noted, however, the medications given were for Infection Prophylaxis and not a treatment for Hematoma. Please review and update response as appropriate. Otherwise, clarify in query response.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 16:11:47
Query 'Per DM CLR: RQ: Response noted, however, the medications given were for Infection Prophylaxis and not a treatment for Hematoma. Please review and update response as appropriate. Otherwise, clarify in query response.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 18:55:14
DataPoint Un-verified.	(b) (4), (b) (6)	17 Dec 2020 18:55:07
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 18:55:07
User opened query 'Per DM CLR: RQ: Response noted, however, the medications given were for Infection Prophylaxis and not a treatment for Hematoma. Please review and update response as appropriate. Otherwise, clarify in query response.' (Site from DM).	(b) (4), (b) (6)	28 Nov 2020 14:44:49
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)	05 Nov 2020 06:52:28
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 'listed as infection prophylaxis' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 19:31:11
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:32:09

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:54

[Concomitant Medication](#)

Audit	User	Time (GMT)
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 08:38:13
User entered 'I'	(b) (4), (b) (6)	12 Oct 2020 17:18:14

US3672199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:54

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:32:09
User entered '0'	(b) (4), (b) (6)	12 Oct 2020 17:18:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:54

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:32:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	12 Oct 2020 17:18:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:54

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:32:09
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 17:18:14

US3672199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:54

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User closed query 'Per DM CLR: Narrative indicates that the subject was prescribed with Ciprofloxacin and Metronidazole to prevent infection. However, there is no corresponding ConMed record that match this information. Please update to record the corresponding medications as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 06:53:06
Query 'Per DM CLR: Narrative indicates that the subject was prescribed with Ciprofloxacin and Metronidazole to prevent infection. However, there is no corresponding ConMed record that match this information. Please update to record the corresponding medications as appropriate. Otherwise, clarify.' answered with 'will update' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 19:31:26
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:32:09
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 16:20:30
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 16:20:24
User closed query 'PV Query: Please report PVD as medical history, as outlined in SAE form.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 16:20:14
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 16:20:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:54

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative indicates that the subject was prescribed with Ciprofloxacin and Metronidazole to prevent infection. However, there is no corresponding ConMed record that match this information. Please update to record the corresponding medications as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 08:37:39
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' answered with 'sent.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 20:13:05
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'please refer to hospital records sent to email and fax.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 18:56:05
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'please refer to hospital discharge summary sent to you.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 18:04:58
Query 'PV Query: Please report PVD as medical history, as outlined in SAE form.' answered with 'added' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 17:50:41
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 14:46:22
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 14:45:49
User opened query 'PV Query: Please report PVD as medical history, as outlined in SAE form.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 14:45:41

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 14:45:29
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	12 Oct 2020 17:20:58
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	12 Oct 2020 17:20:58
User entered 'Subject had angioplasty surgery for medical history of peripheral vascular disease. Subject was hospitalized for hematoma in groin area following angioplasty. Subject had surgery on 06 October 2020 and was discharged 08 October 2020. Subject prescribed Ciprofloxacin and Metronidazole to prevent infection.' reason for change: Per Query Resolution	(b) (4), (b) (6)	12 Oct 2020 17:20:58
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	12 Oct 2020 17:18:14
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 17:18:14

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Folder: Adverse Events

Form: Adverse Events (1)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 17:18:14

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Folder: Adverse Events

Form: Adverse Events (1)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Oct 2020 17:18:14

US3672199

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:22:54

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Oct 2020 17:18:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:54

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:35

US3672199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:54

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest discomfort, LLT: Chest tightness - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Apr 2021 10:47:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Apr 2021 10:47:57
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	09 Apr 2021 20:51:30
Data point term sent to Coder	System	09 Apr 2021 17:52:15
User closed query 'For coding purposes, for the term CHEST TIGHTNESS please specify if this is CARDIAC CHEST PAIN, NON CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain, unknown etiology, etc). ' (Site from System).	System	09 Apr 2021 17:51:25
Query 'For coding purposes, for the term CHEST TIGHTNESS please specify if this is CARDIAC CHEST PAIN, NON CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain, unknown etiology, etc). ' answered with 'updated' (Site from System).	(b) (4), (b) (6)	09 Apr 2021 17:51:25
Data point term sent to Coder	System	09 Apr 2021 17:51:13
Coding entries removed.	(b) (4), (b) (6)	09 Apr 2021 17:51:02
Signature has been broken.	(b) (4), (b) (6)	09 Apr 2021 17:51:02
User entered 'cardiac CHEST TIGHTNESS' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 17:51:02

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'For coding purposes, for the term CHEST TIGHTNESS please specify if this is CARDIAC CHEST PAIN, NON CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain, unknown etiology, etc). ' (Site from System). User signature succeeded.	Coder Import (b) (4) (b) (4)	31 Mar 2021 14:53:09
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest discomfort, LLT: Chest tightness - version MedDRA\\23.0.	Cynthia Strout (b) (4) (b) (4)	19 Mar 2021 13:28:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Mar 2021 17:24:52
Data point term sent to Coder	System	16 Mar 2021 17:24:16
User entered 'CHEST TIGHTNESS'	(b) (4), (b) (6)	16 Mar 2021 17:23:33

US3672199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:54

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered 'No (N)'	(b) (4), (b) (6)	16 Mar 2021 17:23:33

US3672199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:54

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered 'No (N)'	(b) (4), (b) (6)	16 Mar 2021 17:23:33

US3672199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:54

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered 'No (N)'	(b) (4), (b) (6)	16 Mar 2021 17:23:33

US3672199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered '20 Aug 2020'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:23:33

US3672199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:54

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	17 Mar 2021 09:27:27
Query 'Data is required. Please provide.' answered with 'DATA NOT COLLECTED' (Site from System).	(b) (4), (b) (6)	16 Mar 2021 17:28:17
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Mar 2021 17:23:33
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 17:23:33

US3672199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:54

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:35
User entered empty.	System	16 Mar 2021 17:23:33

US3672199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered 'No (N)'	(b) (4), (b) (6)	16 Mar 2021 17:23:33

US3672199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:54

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered '22 Aug 2020'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:23:33

US3672199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:54

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	17 Mar 2021 09:27:37
Query 'Data is required. Please provide.' answered with 'DATA NOT COLLECTED' (Site from System).	(b) (4), (b) (6)	16 Mar 2021 17:28:25
User opened query 'Data is required. Please provide.' (Site from System).	System	16 Mar 2021 17:23:33
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 17:23:33

US3672199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:54

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:35
User entered empty.	System	16 Mar 2021 17:23:33

US3672199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:54

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:23:33

US3672199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:54

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered 'No (N)'	(b) (4), (b) (6)	16 Mar 2021 17:23:33

US3672199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:54

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered '0'	(b) (4), (b) (6)	16 Mar 2021 17:23:33

US3672199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:54

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered '0'	(b) (4), (b) (6)	16 Mar 2021 17:23:33

US3672199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered '0'	(b) (4), (b) (6)	16 Mar 2021 17:23:33

US3672199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:54

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 17:23:33

US3672199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:54

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 17:23:33

US3672199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:54

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 17:23:33

US3672199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:54

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 17:23:33

US3672199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered '0'	(b) (4), (b) (6)	16 Mar 2021 17:23:33

US3672199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered '0'	(b) (4), (b) (6)	16 Mar 2021 17:23:33

US3672199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:54

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered '0'	(b) (4), (b) (6)	16 Mar 2021 17:23:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:54

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Mar 2021 17:27:19
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	16 Mar 2021 17:27:19
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	16 Mar 2021 17:27:19
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 17:23:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:54

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Mar 2021 17:27:19
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	16 Mar 2021 17:27:19
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	16 Mar 2021 17:27:19
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 17:23:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:54

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Mar 2021 17:27:19
User entered 'None (NONE)' reason for change:	(b) (4), (b) (6)	16 Mar 2021 17:27:19
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Mar 2021 17:23:33
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 17:23:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:54

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered 'l'	(b) (4), (b) (6)	16 Mar 2021 17:23:33

US3672199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:54

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered '0'	(b) (4), (b) (6)	16 Mar 2021 17:23:33

US3672199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:54

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered '0'	(b) (4), (b) (6)	16 Mar 2021 17:23:33

US3672199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:54

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	16 Mar 2021 17:23:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:54

[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 12:29:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:23:33

US3672199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:54

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:35
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 17:23:33

US3672199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:54

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:35
User entered '0'	System	16 Mar 2021 17:23:33

US3672199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:54

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:35
User entered '0'	System	16 Mar 2021 17:23:33

US3672199

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:22:54

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:29:35

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:22:54

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin and subcutaneous tissue disorders NEC, HLT: Skin and subcutaneous tissue ulcerations, PT: Skin ulcer, LLT: Skin ulcer - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 11:57:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Mar 2021 11:57:44
Data point term sent to Coder	System	16 Mar 2021 17:26:17
User entered 'SKIN ULCER RIGHT GREAT TOE'	(b) (4), (b) (6)	16 Mar 2021 17:25:34

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:22:54

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Mar 2021 17:25:34

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:22:54

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered 'No (N)'	(b) (4), (b) (6)	16 Mar 2021 17:25:34

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:22:54

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered 'No (N)'	(b) (4), (b) (6)	16 Mar 2021 17:25:34

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered '01 Dec 2020'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:25:34

US3672199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:22:54

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 17:25:34

US3672199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:22:54

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Mar 2021 17:25:34

US3672199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:22:54

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Mar 2021 17:25:34

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:22:54

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 17:25:34

US3672199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:22:54

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 17:25:34

US3672199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:22:54

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Mar 2021 17:25:34

US3672199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:22:54

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	16 Mar 2021 17:25:34

US3672199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:22:54

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered 'No (N)'	(b) (4), (b) (6)	16 Mar 2021 17:25:34

US3672199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:22:54

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered '0'	(b) (4), (b) (6)	16 Mar 2021 17:25:34

US3672199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:22:54

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered '0'	(b) (4), (b) (6)	16 Mar 2021 17:25:34

US3672199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:22:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered '0'	(b) (4), (b) (6)	16 Mar 2021 17:25:34

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:22:54

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 17:25:34

US3672199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:22:54

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 17:25:34

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Folder: Adverse Events

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 17:25:34

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 17:25:34

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Folder: Adverse Events

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered '0'	(b) (4), (b) (6)	16 Mar 2021 17:25:34

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Folder: Adverse Events

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered '0'	(b) (4), (b) (6)	16 Mar 2021 17:25:34

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered '0'	(b) (4), (b) (6)	16 Mar 2021 17:25:34

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	16 Mar 2021 17:25:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Mar 2021 17:25:52
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 17:25:52
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Mar 2021 17:25:34
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 17:25:34

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:22:54

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	16 Mar 2021 17:25:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Mar 2021 17:25:52
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 17:25:52
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Mar 2021 17:25:34
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 17:25:34

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Folder: Adverse Events

Form: Adverse Events (3)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	16 Mar 2021 17:25:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Mar 2021 17:25:52
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 17:25:52
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Mar 2021 17:25:34
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 17:25:34

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Folder: Adverse Events

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered '0'	(b) (4), (b) (6)	16 Mar 2021 17:25:34

US3672199

Folder: Adverse Events

Form: Adverse Events (3)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered 'I'	(b) (4), (b) (6)	16 Mar 2021 17:25:34

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:22:54

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered '0'	(b) (4), (b) (6)	16 Mar 2021 17:25:34

US3672199

Folder: Adverse Events

Form: Adverse Events (3)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	16 Mar 2021 17:25:34

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:22:54

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 17:25:34

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	19 Mar 2021 13:28:16
User entered empty.	(b) (4), (b) (6)	16 Mar 2021 17:25:34

US3672199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:22:54

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Mar 2021 17:25:34

US3672199

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:22:54

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Mar 2021 17:25:34

US3672199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:22:54

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin and subcutaneous tissue disorders NEC, HLT: Skin and subcutaneous tissue ulcerations, PT: Skin ulcer, LLT: Skin ulcer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:07:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:07:05
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	12 Apr 2021 20:44:06
Data point term sent to Coder	System	12 Apr 2021 19:29:49
User entered 'skin ulcer left heel'	(b) (4), (b) (6)	12 Apr 2021 19:29:28

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:22:54

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Apr 2021 19:29:28

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:22:54

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered 'No (N)'	(b) (4), (b) (6)	12 Apr 2021 19:29:28

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Folder: Adverse Events

Form: Adverse Events (4)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered 'No (N)'	(b) (4), (b) (6)	12 Apr 2021 19:29:28

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered '01 Dec 2020'	(b) (4), (b) (6)	12 Apr 2021 19:29:28

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Folder: Adverse Events

Form: Adverse Events (4)

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[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 19:29:28

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Folder: Adverse Events

Form: Adverse Events (4)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 19:29:28

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Folder: Adverse Events

Form: Adverse Events (4)

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[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Apr 2021 19:29:28

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Folder: Adverse Events

Form: Adverse Events (4)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 19:29:28

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Folder: Adverse Events

Form: Adverse Events (4)

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 19:29:28

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:22:54

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 19:29:28

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Folder: Adverse Events

Form: Adverse Events (4)

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	12 Apr 2021 19:29:28

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:22:54

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered 'No (N)'	(b) (4), (b) (6)	12 Apr 2021 19:29:28

US3672199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:22:54

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 19:29:28

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Folder: Adverse Events

Form: Adverse Events (4)

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 19:29:28

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Folder: Adverse Events

Form: Adverse Events (4)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 19:29:28

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 19:29:28

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Form: Adverse Events (4)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 19:29:28

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Folder: Adverse Events

Form: Adverse Events (4)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 19:29:28

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 19:29:28

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Folder: Adverse Events

Form: Adverse Events (4)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 19:29:28

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Folder: Adverse Events

Form: Adverse Events (4)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 19:29:28

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Folder: Adverse Events

Form: Adverse Events (4)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 19:29:28

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:22:54

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	12 Apr 2021 19:29:28

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:22:54

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	12 Apr 2021 19:29:28

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:22:54

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	12 Apr 2021 19:29:28

US3672199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:22:54

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 19:29:28

US3672199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:22:54

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered 'I'	(b) (4), (b) (6)	12 Apr 2021 19:29:28

US3672199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:22:54

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered '0'	(b) (4), (b) (6)	12 Apr 2021 19:29:28

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:22:54

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	12 Apr 2021 19:29:28

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:22:54

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 19:29:28

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:22:54

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:18:46
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 19:29:28

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:22:54

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Apr 2021 19:29:28

US3672199

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:22:54

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 19:29:28

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:06:28
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:01:14
User closed query 'Per ETRTR: According to SAE "Hematoma R Groin" page, medication was dosed for SAE. Please add Medication dosing details for SAE "Hematoma R Groin" within ConMeds page, thanks.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 19:54:34
Query 'Per ETRTR: According to SAE "Hematoma R Groin" page, medication was dosed for SAE. Please add Medication dosing details for SAE "Hematoma R Groin" within ConMeds page, thanks.' answered with 'conmeds related to the AE recorded in conmeds chart' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 15:30:36
User opened query 'Per ETRTR: According to SAE "Hematoma R Groin" page, medication was dosed for SAE. Please add Medication dosing details for SAE "Hematoma R Groin" within ConMeds page, thanks.' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 22:12:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 13:57:49

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL TARTRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 07:45:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 07:45:08
Data point term sent to Coder	System	21 Aug 2020 13:59:59
User entered 'METOPROLOL TARTATE'	(b) (4), (b) (6)	21 Aug 2020 13:59:26

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 13:59:26

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'HTN'	(b) (4), (b) (6)	21 Aug 2020 13:59:26

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered '25'	(b) (4), (b) (6)	21 Aug 2020 13:59:26

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Aug 2020 13:59:26

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:59:26

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'twice daily (BID)'	(b) (4), (b) (6)	21 Aug 2020 13:59:26

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:59:26

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 13:59:26

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:54

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:59:26

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'UN UNK 2010'	(b) (4), (b) (6)	21 Aug 2020 13:59:26

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:59:26

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 13:59:26

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:59:26

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 13:59:26

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Aug 2020 13:59:26

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 13:59:26

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:22:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 13:59:26

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:39
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:03:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 14:03:20
Data point term sent to Coder	System	21 Aug 2020 14:02:10
User entered 'TAMSULOSIN'	(b) (4), (b) (6)	21 Aug 2020 14:01:40

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:39
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:01:40

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:39
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'BPH'	(b) (4), (b) (6)	21 Aug 2020 14:01:40

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:39
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered '0.4'	(b) (4), (b) (6)	21 Aug 2020 14:01:40

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:39
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Aug 2020 14:01:40

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:54

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:39
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:01:40

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:39
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Aug 2020 14:01:40

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:39
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:01:40

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:39
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 14:01:40

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:54

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:39
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:01:40

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:39
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'UN UNK 2010'	(b) (4), (b) (6)	21 Aug 2020 14:01:40

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:39
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:01:40

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:39
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	04 Nov 2020 20:50:50
User closed query 'Per source, the end date is 01Sep2020. please verify and update.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 20:50:47
Query 'Per source, the end date is 01Sep2020. please verify and update.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 19:35:27
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 19:35:22
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Nov 2020 19:35:22
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User opened query 'Per source, the end date is 01Sep2020. please verify and update.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 18:10:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:01:40

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:39
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 20:50:53
DataPoint Un-verified.	(b) (4), (b) (6)	04 Nov 2020 19:35:22
User entered '01 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Nov 2020 19:35:22
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:01:40

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:39
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:01:40

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:39
User entered '1'	System	21 Aug 2020 14:01:40

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:39
User entered '1'	System	21 Aug 2020 14:01:40

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:22:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:39
User entered '804 (804)'	System	21 Aug 2020 14:01:40

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 14:04:23
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	21 Aug 2020 14:04:23
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	21 Aug 2020 14:03:13
User entered 'ATROVASTATIN'	(b) (4), (b) (6)	21 Aug 2020 14:02:35

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	(b) (4), (b) (6)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:02:35

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'HLD'	(b) (4), (b) (6)	21 Aug 2020 14:02:35

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered '40'	(b) (4), (b) (6)	21 Aug 2020 14:02:35

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Aug 2020 14:02:35

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:54

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:02:35

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'twice daily (BID)'	(b) (4), (b) (6)	21 Aug 2020 14:02:35

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:02:35

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 14:02:35

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:02:35

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'UN UNK 2010'	(b) (4), (b) (6)	21 Aug 2020 14:02:35

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:02:35

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:02:35

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:02:35

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:02:35

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Aug 2020 14:02:35

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:02:35

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:22:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 14:02:35

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:54

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 04:51:40
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Oct 2020 04:51:40
	(b) (4)	
Data point term sent to Coder	System	29 Oct 2020 15:39:34
Coding entries removed.	(b) (4), (b) (6)	29 Oct 2020 15:39:03
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 14:08:16
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 14:08:16
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 14:07:24
User entered 'ASPIRIN'	(b) (4), (b) (6)	21 Aug 2020 14:07:12

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:07:12

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User closed query 'Per CDM Re-Query: Thank you. As per your comment, please indicate the cardiac condition that is to be prevented, and add the term prophylaxis. Thank you' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 08:42:07
Query 'Per CDM Re-Query: Thank you. As per your comment, please indicate the cardiac condition that is to be prevented, and add the term prophylaxis. Thank you' answered with 'indication updated' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 15:39:13
User entered 'Cardiovascular disease prophylaxis' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Oct 2020 15:39:03
User opened query 'Per CDM Re-Query: Thank you. As per your comment, please indicate the cardiac condition that is to be prevented, and add the term prophylaxis. Thank you' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 15:32:34
User closed query 'Per DM CLR: Please review and ensure that the Indication reflects a medical condition or diagnosis. Update eCRF as appropriate. Otherwise, if used as prophylaxis please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication (e.g., NAUSEA prophylaxis). Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 15:32:34

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:54

Indication

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review and ensure that the Indication reflects a medical condition or diagnosis. Update eCRF as appropriate. Otherwise, if used as prophylaxis please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication (e.g., NAUSEA prophylaxis). Update Con Med eCRF as appropriate. ' answered with 'IF IT WERE TAKEN TO PREVENT A CONDITION THEY HAD, WE WOULD HAVE INCLUDED THAT. TAKING ASPIRIN FOR CARDIAC PROPHYLAXIS IS NOT AN INDICATION THAT THEY HAVE A CARDIAC CONDITION, IT IS AN INDICATION THAT THEY WISH TO PREVENT A CARDIAC CONDITION' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 19:13:29
User opened query 'Per DM CLR: Please review and ensure that the Indication reflects a medical condition or diagnosis. Update eCRF as appropriate. Otherwise, if used as prophylaxis please update the indication of this medication to include the underlying medical condition/diagnosis to support the prophylactic indication (e.g., NAUSEA prophylaxis). Update Con Med eCRF as appropriate.	(b) (4), (b) (6)	04 Oct 2020 11:20:48
' (Site from DM). User entered 'CARDIAC'	(b) (4), (b) (6)	21 Aug 2020 14:07:12

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered '81'	(b) (4), (b) (6)	21 Aug 2020 14:07:12

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Aug 2020 14:07:12

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:07:12

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Aug 2020 14:07:12

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:07:12

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 14:07:12

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:54

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:07:12

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'UN UNK 2010'	(b) (4), (b) (6)	21 Aug 2020 14:07:12

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:07:12

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:07:12

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:07:12

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:07:12

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:07:12

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:07:12

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:22:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 14:07:12

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: EZETIMIBE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Aug 2020 13:26:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	24 Aug 2020 13:26:33
Data point term sent to Coder	System	21 Aug 2020 14:09:28
User entered 'EZETIMIBE'	(b) (4), (b) (6)	21 Aug 2020 14:09:11

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:09:11

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'HLD'	(b) (4), (b) (6)	21 Aug 2020 14:09:11

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered '25'	(b) (4), (b) (6)	21 Aug 2020 14:09:11

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Aug 2020 14:09:11

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:54

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:09:11

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Aug 2020 14:09:11

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:09:11

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 14:09:11

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:09:11

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'UN UNK 2010'	(b) (4), (b) (6)	21 Aug 2020 14:09:11

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:09:11

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:09:11

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:09:11

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:09:11

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:09:11

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:09:11

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:22:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 14:09:11

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 07:37:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 07:37:10
Data point term sent to Coder	System	21 Aug 2020 14:15:46
User entered 'MELOXICAM'	(b) (4), (b) (6)	21 Aug 2020 14:15:37

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:15:37

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'B/L TOE PAIN'	(b) (4), (b) (6)	21 Aug 2020 14:15:37

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered '15'	(b) (4), (b) (6)	21 Aug 2020 14:15:37

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Aug 2020 14:15:37

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:54

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:15:37

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Aug 2020 14:15:37

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:15:37

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 14:15:37

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:15:37

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'un UNK 2010'	(b) (4), (b) (6)	21 Aug 2020 14:15:37

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:15:37

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:15:37

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:15:37

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:15:37

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:15:37

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:15:37

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:22:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 14:15:37

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 07:34:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 07:34:08
Data point term sent to Coder	System	21 Aug 2020 14:17:51
User entered 'METFORMIN'	(b) (4), (b) (6)	21 Aug 2020 14:17:17

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:17:17

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'PREDIABESTES'	(b) (4), (b) (6)	21 Aug 2020 14:17:17

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered '500'	(b) (4), (b) (6)	21 Aug 2020 14:17:17

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Aug 2020 14:17:17

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:54

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:17:17

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Aug 2020 14:17:17

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:17:17

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 14:17:17

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:17:17

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'UN UNK 2010'	(b) (4), (b) (6)	21 Aug 2020 14:17:17

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 14:17:17

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:17:17

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:17:17

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:17:17

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:17:17

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 14:17:17

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:22:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 14:17:17

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 18:03:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 18:03:55
Data point term sent to Coder	System	28 Oct 2020 15:28:49
User entered 'Ciprofloxacin'	(b) (4), (b) (6)	28 Oct 2020 15:28:39

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 15:28:39

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'Infection prophylaxis'	(b) (4), (b) (6)	28 Oct 2020 15:28:39

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered '500'	(b) (4), (b) (6)	28 Oct 2020 15:28:39

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Oct 2020 15:28:39

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:54

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 15:28:39

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'three times daily (TID)'	(b) (4), (b) (6)	28 Oct 2020 15:28:39

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 15:28:39

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Oct 2020 15:28:39

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:54

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 15:28:39

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered '8 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 15:28:39

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 15:28:39

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 15:28:39

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 15:28:39

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 15:28:39

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	28 Oct 2020 15:28:39

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 15:28:39

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:22:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Oct 2020 15:28:39

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 18:06:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 18:06:07
Data point term sent to Coder	System	28 Oct 2020 15:29:50
User entered 'Metronidazole'	(b) (4), (b) (6)	28 Oct 2020 15:29:28

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 15:29:28

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'Infection prophylaxis'	(b) (4), (b) (6)	28 Oct 2020 15:29:28

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered '500'	(b) (4), (b) (6)	28 Oct 2020 15:29:28

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Oct 2020 15:29:28

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:54

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 15:29:28

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'twice daily (BID)'	(b) (4), (b) (6)	28 Oct 2020 15:29:28

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 15:29:28

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Oct 2020 15:29:28

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:54

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 15:29:28

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered '8 Oct 2020'	(b) (4), (b) (6)	28 Oct 2020 15:29:28

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered '0'	(b) (4), (b) (6)	28 Oct 2020 15:29:28

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Oct 2020 15:29:28

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered empty.	(b) (4), (b) (6)	28 Oct 2020 15:29:28

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:28:12
User entered 'No (N)'	(b) (4), (b) (6)	28 Oct 2020 15:29:28

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	28 Oct 2020 15:29:28

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Oct 2020 15:29:28

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:22:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Oct 2020 15:29:28

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 14:44:42
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 19:34:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 19:34:36
Data point term sent to Coder	System	04 Nov 2020 19:33:46
User entered 'Hydrochlorothiazide'	(b) (4), (b) (6)	04 Nov 2020 19:33:35

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 14:44:40
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 19:33:35

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:44:36
User entered 'hypertension'	(b) (4), (b) (6)	04 Nov 2020 19:33:35

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 14:44:38
User entered '25'	(b) (4), (b) (6)	04 Nov 2020 19:33:35

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 14:44:35
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Nov 2020 19:33:35

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 14:44:33
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 19:33:35

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:44:31
User entered 'once daily (QD)'	(b) (4), (b) (6)	04 Nov 2020 19:33:35

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 14:44:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 19:33:35

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 14:44:28
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Nov 2020 19:33:35

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:44:26
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 19:33:35

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 14:44:24
User entered 'un UNK 2010'	(b) (4), (b) (6)	04 Nov 2020 19:33:35

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 14:44:23
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 19:33:35

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 14:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 19:33:35

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:44:20
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 19:33:35

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:44:18
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 19:33:35

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 19:33:35

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 19:33:35

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:22:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Nov 2020 19:33:35

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:54

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN SODIUM;TAZOBACTAM SODIUM, PRODUCTSYNONYM: ZOSYN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 19:49:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 19:49:54
Data point term sent to Coder Coding entries removed.	System	19 Feb 2021 19:49:28
	Patty Howenstine (b) (4)	19 Feb 2021 19:49:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 14:45:14
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN SODIUM;TAZOBACTAM SODIUM, PRODUCTSYNONYM: ZOSYN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 14:06:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 14:06:18
Data point term sent to Coder	System	05 Nov 2020 14:05:29
User entered 'zosyn'	(b) (4), (b) (6)	05 Nov 2020 14:04:49

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 14:45:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 14:04:49

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User closed query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' answered with 'Changed Indication. It is prophylactic medication.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 04:05:19
Query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' answered with 'Changed Indication. It is prophylactic medication.' (Site from DM).	Patty Howenstine (b) (4)	19 Feb 2021 19:49:53
DataPoint Un-verified.	(b) (4)	
User entered 'Post Angioplasty Infection Prevention' reason for change: Data Entry Error	Patty Howenstine (b) (4)	19 Feb 2021 19:49:08
User opened query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' (Site from DM).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 13:57:19
User entered 'bowel ischemia'	(b) (4), (b) (6)	05 Nov 2020 14:45:14
	(b) (4), (b) (6)	05 Nov 2020 14:04:49

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User closed query 'Per CDM: Please follow CRF Guidelines for entering unknown (UNK) Doses. Thank you' (Site from DM).	(b) (4)	05 Mar 2021 11:12:13
Query 'Per CDM: Please follow CRF Guidelines for entering unknown (UNK) Doses. Thank you' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 15:25:52
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 15:25:39
User entered 'UNK' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 15:25:39
User opened query 'Per CDM: Please follow CRF Guidelines for entering unknown (UNK) Doses. Thank you' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 16:45:49
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	06 Nov 2020 16:30:03
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:45:14
Query 'Data is required. Please complete.' answered with 'unknown' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 14:04:57
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 14:04:49
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 14:04:49

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	06 Nov 2020 16:30:05
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:45:14
Query 'Data is required. Please complete.' answered with 'unknown' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 14:04:59
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 14:04:49
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 14:04:49

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 14:45:14
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 14:04:49

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	06 Nov 2020 16:30:07
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:45:14
Query 'Data is required. Please complete.' answered with 'unknown' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 14:05:03
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 14:04:49
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 14:04:49

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:45:14
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 14:04:49

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:45:14
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	05 Nov 2020 14:04:49

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:54

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:45:14
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 14:04:49

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	05 Nov 2020 14:45:14
User entered '06 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 14:04:49

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:45:14
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 14:04:49

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:45:14
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 14:04:49

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:45:14
User entered '06 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 14:04:49

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:44
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:45:14
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 14:04:49

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:44
User entered empty.	System	05 Nov 2020 14:04:49

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:44
User entered empty.	System	05 Nov 2020 14:04:49

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:22:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:44
User entered empty.	System	05 Nov 2020 14:04:49

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:54

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:48
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, PRODUCT: I.V. SOLUTIONS - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 12:46:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 12:46:22
Data point term sent to Coder	System	12 Apr 2021 19:27:47
User closed query 'For coding purposes, please complete the medication reported and amend/update the term accordingly to enable coding' (Site from System).	System	12 Apr 2021 19:27:25
Query 'For coding purposes, please complete the medication reported and amend/update the term accordingly to enable coding' answered with 'confirm as reported by patient' (Site from System).	(b) (4), (b) (6)	12 Apr 2021 19:27:25
User opened query 'For coding purposes, please complete the medication reported and amend/update the term accordingly to enable coding' (Site from System).	Coder Import (b) (4) (b) (4)	08 Apr 2021 07:26:34
User signature succeeded.	Cynthia Strout (b) (4) (b) (4)	05 Mar 2021 18:00:43
Data point term sent to Coder	System	19 Feb 2021 19:50:28
Coding entries removed.	Patty Howenstine (b) (4) (b) (4)	19 Feb 2021 19:50:23
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: GYNECOLOGICAL ANTIINFECTIVES AND ANTISEPTICS, ATC: ANTIINFECTIVES AND ANTISEPTICS, EXCL. COMBINATIONS WITH CORTICOSTEROIDS, ATC: ORGANIC ACIDS, PRODUCT: LACTIC ACID - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 12:15:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 12:15:18
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:45:14

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	05 Nov 2020 14:06:32
User entered 'lactate'	(b) (4), (b) (6)	05 Nov 2020 14:05:34

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:45:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 14:05:34

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User closed query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 04:07:31
Query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' answered with 'changed indication' (Site from DM).	Patty Howenstine (b) (4) (b) (4)	19 Feb 2021 19:50:29
DataPoint Un-verified.	Patty Howenstine (b) (4) (b) (4)	19 Feb 2021 19:50:23
User entered 'post angioplasty infection prevention' reason for change: Data Entry Error	Patty Howenstine (b) (4) (b) (4)	19 Feb 2021 19:50:23
User opened query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 13:57:47
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:45:14
User entered 'bowel ischemia'	(b) (4), (b) (6)	05 Nov 2020 14:05:34

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User closed query 'Per CDM: Please follow CRF Guidelines on how to enter unknown (UNK) Doses. Thank you' (Site from DM).	(b) (4)	05 Mar 2021 11:12:33
Query 'Per CDM: Please follow CRF Guidelines on how to enter unknown (UNK) Doses. Thank you' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 15:26:10
DataPoint Un-verified.	(b) (4), (b) (6)	04 Mar 2021 15:26:01
User entered 'UNK' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Mar 2021 15:26:01
User opened query 'Per CDM: Please follow CRF Guidelines on how to enter unknown (UNK) Doses. Thank you' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 17:01:27
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	06 Nov 2020 16:30:50
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:45:14
Query 'Data is required. Please complete.' answered with 'unknown' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 14:05:39
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 14:05:34
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 14:05:34

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	06 Nov 2020 16:30:52
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:45:14
Query 'Data is required. Please complete.' answered with 'unknown' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 14:05:41
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 14:05:34
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 14:05:34

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:54

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:45:14
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 14:05:34

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	06 Nov 2020 16:30:58
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:45:14
Query 'Data is required. Please complete.' answered with 'unknown' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 14:05:44
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 14:05:34
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 14:05:34

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:45:14
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 14:05:34

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:45:14
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	05 Nov 2020 14:05:34

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:54

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:45:14
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 14:05:34

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 14:45:14
User entered '06 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 14:05:34

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:45:14
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 14:05:34

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:45:14
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 14:05:34

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:45:14
User entered '06 Oct 2020'	(b) (4), (b) (6)	05 Nov 2020 14:05:34

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:48
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:45:14
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 14:05:34

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:48
User entered empty.	System	05 Nov 2020 14:05:34

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:48
User entered empty.	System	05 Nov 2020 14:05:34

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:22:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:48
User entered empty.	System	05 Nov 2020 14:05:34

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:01:26
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 19:35:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 19:35:21
Data point term sent to Coder	System	05 Nov 2020 19:33:58
User entered 'TAMSULOSIN'	(b) (4), (b) (6)	05 Nov 2020 19:33:38

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:01:26
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 19:33:38

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:01:26
User entered 'BPH'	(b) (4), (b) (6)	05 Nov 2020 19:33:38

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:01:26
User entered '.4'	(b) (4), (b) (6)	05 Nov 2020 19:33:38

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:01:26
User entered 'mg (mg)'	(b) (4), (b) (6)	05 Nov 2020 19:33:38

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:01:26
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:33:38

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:01:26
User entered 'twice daily (BID)'	(b) (4), (b) (6)	05 Nov 2020 19:33:38

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:01:26
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:33:38

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:01:26
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Nov 2020 19:33:38

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:01:26
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:33:38

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:01:26
User entered '02 Sep 2020'	(b) (4), (b) (6)	05 Nov 2020 19:33:38

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:01:26
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 19:33:38

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:01:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 19:33:38

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 20:01:26
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:33:38

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 20:01:26
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 19:33:38

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Nov 2020 19:33:38

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 19:33:38

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:22:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 19:33:38

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:54

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:51
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
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)	17 Mar 2021 07:26:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 07:26:39
Data point term sent to Coder	System	16 Mar 2021 17:19:13
User entered 'AMOXICILLIN'	(b) (4), (b) (6)	16 Mar 2021 17:19:08

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:51
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:19:08

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:51
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered 'SKIN ULCER RIGHT GREAT TOE'	(b) (4), (b) (6)	16 Mar 2021 17:19:08

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:51
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered '500'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:19:08

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:51
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:19:08

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:54

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:51
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:19:08

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:51
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered 'three times daily (TID)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:19:08

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:51
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:19:08

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:51
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:19:08

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:54

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:51
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:19:08

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:51
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered '03 Mar 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:19:08

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:51
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered '0'	(b) (4), (b) (6)	16 Mar 2021 17:19:08

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:51
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:19:08

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:51
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered '10 Mar 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:19:08

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:51
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:19:08

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:51
User entered '3'	System	16 Mar 2021 17:19:08

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:51
User entered '1'	System	16 Mar 2021 17:19:08

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:22:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:15:51
User entered '804 (804)'	System	16 Mar 2021 17:19:08

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: BACTRIM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Mar 2021 17:20:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Mar 2021 17:20:52
Data point term sent to Coder	System	16 Mar 2021 17:20:13
User entered 'BACTRIM'	(b) (4), (b) (6)	16 Mar 2021 17:20:05

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:20:05

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:54

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Cynthia Strout (b) (4)	13 Apr 2021 07:53:22 12 Apr 2021 20:44:06
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'added' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 19:27:52
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 04:15:25
User entered 'SKIN ULCER LEFT HEEL'	(b) (4), (b) (6)	16 Mar 2021 17:20:05

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	20 Apr 2021 15:32:48
User closed query 'Per CDM, DM CLR RQ: Site's response noted. Kindly review and update dosage or provide further clarification. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Apr 2021 06:40:15
Query 'Per CDM, DM CLR RQ: Site's response noted. Kindly review and update dosage or provide further clarification. Thank you. ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 13:36:41
Signature has been broken.	(b) (4), (b) (6)	16 Apr 2021 13:36:22
User entered '160' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 13:36:22
User opened query 'Per CDM, DM CLR RQ: Site's response noted. Kindly review and update dosage or provide further clarification. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 13:11:45
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 13:11:45
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'perpt report' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:28:11
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 04:15:54
User entered '1600'	(b) (4), (b) (6)	16 Mar 2021 17:20:05

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
Un-reviewed for Data Management.	(b) (4)	
	(b) (4), (b) (6)	04 Apr 2021 04:16:03
Reviewed for Data Management.	(b) (4), (b) (6)	04 Apr 2021 04:16:00
User entered 'mg (mg)'	(b) (4), (b) (6)	16 Mar 2021 17:20:05

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:20:05

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:20:05

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:20:05

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:20:05

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:20:05

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:54

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

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered '16 Mar 2021'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:20:05

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:20:05

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:20:05

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:20:05

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	12 Apr 2021 20:44:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:20:05

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Mar 2021 17:20:05

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Mar 2021 17:20:05

US3672199

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:22:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Mar 2021 17:20:05

US3672199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:22:54

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:06:28
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:18:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 16:57:28

US3672199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:22:54

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:20:51
User entered '6 Oct 2020'	(b) (4), (b) (6)	12 Oct 2020 16:59:27

US3672199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:22:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:20:51
User entered 'Angioplasty Surgery'	(b) (4), (b) (6)	12 Oct 2020 16:59:27

US3672199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:22:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:20:51
User entered 'Medical History (MH)'	(b) (4), (b) (6)	12 Oct 2020 16:59:27

US3672199

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:22:54

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:20:51
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 16:59:27

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'USA-US116-2020-MRNA-1273-P301000003'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'Yes (Y)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'No (N)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'No (N)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'Yes (Y)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'No (N)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'No (N)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'No (N)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'Cynthia'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'Strout'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered '1156 Bowman Road'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'Mount Pleasant'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	18 Dec 2020 15:30:36
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:29:56
Un-reviewed for Safety.	System	02 Nov 2020 16:22:46
User entered empty.	System	02 Nov 2020 16:22:46
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 16:22:30
User entered 'SC'	(b) (4), (b) (6)	30 Oct 2020 18:03:27

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered '29464'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:11:05
User entered 'US'	System	13 Oct 2020 13:49:47

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Jan 2021 16:29:34
User entered '4'	System	18 Dec 2020 15:30:48
User entered '3'	System	02 Nov 2020 16:22:46
User entered '2'	System	29 Oct 2020 15:11:15
User entered '1'	System	13 Oct 2020 13:49:47

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered		
'USA-US116-2020-MRNA-1273-P301000003'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'Yes (Y)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'No (N)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'No (N)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'Yes (Y)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'No (N)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'No (N)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'No (N)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'Cynthia'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'Strout'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered '1156 Bowman Road'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'Mount Pleasant'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	18 Dec 2020 15:30:36
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:29:56
Un-reviewed for Safety.	System	02 Nov 2020 16:22:46
User entered empty.	System	02 Nov 2020 16:22:46
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 16:22:30
User entered 'SC'	(b) (4), (b) (6)	30 Oct 2020 18:03:27

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered '29464'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:11:05
User entered 'US'	System	13 Oct 2020 13:49:47

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Jan 2021 16:29:34
User entered '4'	System	18 Dec 2020 15:30:48
User entered '3'	System	02 Nov 2020 16:22:46
User entered '2'	System	29 Oct 2020 15:11:15
User entered '1'	System	13 Oct 2020 13:49:47

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:22:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
User entered '13/Oct/2020 13:49'	System	13 Oct 2020 13:49:47

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:22:54

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:11:05
User entered 'I'	(b) (4), (b) (6)	13 Oct 2020 13:49:47

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'USA-US116-2020-MRNA-1273-P301000003'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'Yes (Y)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'No (N)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'No (N)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'Yes (Y)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'No (N)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'No (N)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'No (N)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'Cynthia'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'Strout'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered '1156 Bowman Road'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'Mount Pleasant'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	18 Dec 2020 15:30:36
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:29:56
Un-reviewed for Safety.	System	02 Nov 2020 16:22:46
User entered empty.	System	02 Nov 2020 16:22:46
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 16:22:30
User entered 'SC'	(b) (4), (b) (6)	30 Oct 2020 18:03:27

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered '29464'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:11:05
User entered 'US'	System	13 Oct 2020 13:49:47

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Jan 2021 16:29:34
User entered '4'	System	18 Dec 2020 15:30:48
User entered '3'	System	02 Nov 2020 16:22:46
User entered '2'	System	29 Oct 2020 15:11:15
User entered '1'	System	13 Oct 2020 13:49:47

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:22:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
User entered '29/Oct/2020 11:11'	System	29 Oct 2020 15:11:15

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:22:54

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 16:22:30
User entered 'I'	(b) (4), (b) (6)	29 Oct 2020 15:11:15

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered		
'USA-US116-2020-MRNA-1273-P301000003'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'Yes (Y)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'No (N)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'No (N)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'Yes (Y)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'No (N)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'No (N)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'No (N)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'Cynthia'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'Strout'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered '1156 Bowman Road'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'Mount Pleasant'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	18 Dec 2020 15:30:36
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:29:56
Un-reviewed for Safety.	System	02 Nov 2020 16:22:46
User entered empty.	System	02 Nov 2020 16:22:46
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 16:22:30
User entered 'SC'	(b) (4), (b) (6)	30 Oct 2020 18:03:27

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered '29464'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:11:05
User entered 'US'	System	13 Oct 2020 13:49:47

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Jan 2021 16:29:34
User entered '4'	System	18 Dec 2020 15:30:48
User entered '3'	System	02 Nov 2020 16:22:46
User entered '2'	System	29 Oct 2020 15:11:15
User entered '1'	System	13 Oct 2020 13:49:47

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:22:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
User entered '02/Nov/2020 16:22'	System	02 Nov 2020 16:22:46

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:22:54

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	18 Dec 2020 15:30:36
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:29:56
User entered 'I'	(b) (4), (b) (6)	02 Nov 2020 16:22:46

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered		
'USA-US116-2020-MRNA-1273-P301000003'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'Yes (Y)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'No (N)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'No (N)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'Yes (Y)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'No (N)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'No (N)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'No (N)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'Cynthia'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'Strout'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered '1156 Bowman Road'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'Mount Pleasant'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	18 Dec 2020 15:30:36
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:29:56
Un-reviewed for Safety.	System	02 Nov 2020 16:22:46
User entered empty.	System	02 Nov 2020 16:22:46
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 16:22:30
User entered 'SC'	(b) (4), (b) (6)	30 Oct 2020 18:03:27

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered '29464'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:11:05
User entered 'US'	System	13 Oct 2020 13:49:47

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Jan 2021 16:29:34
User entered '4'	System	18 Dec 2020 15:30:48
User entered '3'	System	02 Nov 2020 16:22:46
User entered '2'	System	29 Oct 2020 15:11:15
User entered '1'	System	13 Oct 2020 13:49:47

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:22:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:19:16
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '18/Dec/2020 15:30'	(b) (4) System	18 Dec 2020 15:30:48

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:22:54

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:19:18
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 16:29:15
User entered 'I'	(b) (4), (b) (6)	18 Dec 2020 15:30:48

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'USA-US116-2020-MRNA-1273-P301000003'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'Yes (Y)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'No (N)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'No (N)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'Yes (Y)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'No (N)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'No (N)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'No (N)'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'Cynthia'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'Strout'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered '1156 Bowman Road'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered 'Mount Pleasant'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	18 Dec 2020 15:30:36
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:29:56
Un-reviewed for Safety.	System	02 Nov 2020 16:22:46
User entered empty.	System	02 Nov 2020 16:22:46
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 16:22:30
User entered 'SC'	(b) (4), (b) (6)	30 Oct 2020 18:03:27

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	13 Oct 2020 13:42:17
User entered '29464'	System	13 Oct 2020 13:41:33

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:29:56
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 15:11:05
User entered 'US'	System	13 Oct 2020 13:49:47

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:22:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	12 Jan 2021 16:29:34
User entered '4'	System	18 Dec 2020 15:30:48
User entered '3'	System	02 Nov 2020 16:22:46
User entered '2'	System	29 Oct 2020 15:11:15
User entered '1'	System	13 Oct 2020 13:49:47

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:22:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered '12/Jan/2021 16:29'	(b) (4) System	12 Jan 2021 16:29:34

US3672199

Folder: SAE USA-US116-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:22:54

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:00:43
User entered 'I'	(b) (4) (b) (4), (b) (6)	12 Jan 2021 16:29:34