

US3672278 (Prod: Coastal Carolina Research Center)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:25:56

All time stamps listed in this document are displayed in GMT

US3672278

Form: Participant Creation

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

Generated On: 10 Jun 2021 09:25:56

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Participant ID

US3672278

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

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US3672278

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 20:08:44

Generated On: 10 Jun 2021 09:25:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 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 20:08:44

Generated On: 10 Jun 2021 09:25:56

Date of Birth (MMM yyyy)	(b) (6) 1942
Age	78
Age Units	YEARS
Age (Derived)	78
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 20:08:44

Generated On: 10 Jun 2021 09:25:56

Date of Informed Consent ( <i>dd MMM yyyy</i> )	24 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 20:08:44

Generated On: 10 Jun 2021 09:25:56

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 20:08:44

Generated On: 10 Jun 2021 09:25:56

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 08 Apr 2021 21:43:21

Generated On: 10 Jun 2021 09:25:56

Condition	MYOCARDIAL INFARCTION
Start date (dd MMM yyyy)	UN UNK 1989
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1989
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1989
Start Year (derived)	1989
Stop Month and Year (derived)	JAN 1989
Stop Year (derived)	1989



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 08 Apr 2021 21:43:21

Generated On: 10 Jun 2021 09:25:56

Condition	TYPE 2 DIABETES
Start date (dd MMM yyyy)	UN UNK 2014
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 08 Apr 2021 21:43:21

Generated On: 10 Jun 2021 09:25:56

Condition	LEG CRAMPS
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3672278

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 08 Apr 2021 21:43:21

Generated On: 10 Jun 2021 09:25:56

Condition	ALLERGIC RHINITIS
Start date (dd MMM yyyy)	UN UNK 1989
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 1989
Start Year (derived)	1989
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 08 Apr 2021 21:43:21

Generated On: 10 Jun 2021 09:25:56

Condition	DEFIBRILLATOR IMPLANT
Start date (dd MMM yyyy)	UN DEC 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 08 Apr 2021 21:43:21

Generated On: 10 Jun 2021 09:25:56

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	UN DEC 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 08 Apr 2021 21:43:21

Generated On: 10 Jun 2021 09:25:56

Condition	CONGESTIVE HEART FAILURE
Start date (dd MMM yyyy)	UN DEC 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 08 Apr 2021 21:43:21

Generated On: 10 Jun 2021 09:25:56

Condition	CEREBRAL VASCULAR DISEASE
Start date (dd MMM yyyy)	UN UNK 2002
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 2002
Start Year (derived)	2002
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 08 Apr 2021 21:43:21

Generated On: 10 Jun 2021 09:25:56

Condition	OBSTRUCTIVE SLEEP APNEA
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 20:08:44

Generated On: 10 Jun 2021 09:25:56

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	24 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	14:15 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 14:15
Height ( <i>xxx.x</i> )	177.5 cm
Weight ( <i>xxx.x</i> )	95.2 kg
BMI ( <i>xxx.x</i> )	30.21623 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	97.6 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	ND - Not Done
Pulse ( <i>xxx</i> )	72 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	67 mmHg
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 20:08:44

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 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 20:08:44

Generated On: 10 Jun 2021 09:25:56

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 20:08:44

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 20:08:44

Generated On: 10 Jun 2021 09:25:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 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 20:08:44

Generated On: 10 Jun 2021 09:25:56

What was the date of randomization? (dd MMM yyyy) 31 AUG 2020

What was the participant's randomization number? 188656

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 20:08:44

Generated On: 10 Jun 2021 09:25:56

Height	177.5 cm
Weight	96.8 kg

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 20:08:44

Generated On: 10 Jun 2021 09:25:56

Height	177.5 cm
Weight	96.8 kg
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)	31 AUG 2020
Time of assessment (00:00-23:59)	10:32 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 10:32
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)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	58 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 20:08:44

Generated On: 10 Jun 2021 09:25:56

Height	177.5 cm
Weight	96.8 kg
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)	31 AUG 2020
Time of assessment (00:00-23:59)	12:04 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 12:04
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	91 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 20:08:44

Generated On: 10 Jun 2021 09:25:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 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: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 20:08:44

Generated On: 10 Jun 2021 09:25:56

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) 31 AUG 2020

What was the treatment time? (00:00-23:59) 11:25 (24 HR)

Treatment Date and Time (derived) 31 AUG 2020 11:25

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 20:08:44

Generated On: 10 Jun 2021 09:25:56

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

31 AUG 2020

Collection time (00:00-23:59)

11:07 (24 HR)

Collection date and time (derived)

31 AUG 2020 11:07

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 20:08:44

Generated On: 10 Jun 2021 09:25:56

Collection date (dd MMM yyyy)			31 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:49	31 AUG 2020 10:49
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:08:44

Generated On: 10 Jun 2021 09:25:56

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 09:25:56

**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

31 AUG 2020 11:58

PC Open Date & Time

31 AUG 2020 11:45

PC Close Date & Time

31 AUG 2020 14:15

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.7 °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	01 SEP 2020 00:04
PC Open Date & Time	31 AUG 2020 15:10
PC Close Date & Time	01 SEP 2020 11:59



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:25:56

**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

96.1 °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

01 SEP 2020 22:58

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:25:56

**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

03 SEP 2020 00:03

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 23:38

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:25:56

**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

97.2 °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

04 SEP 2020 22:56

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:25:56

**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

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 23:13

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:25:56

**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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 23:10

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

4

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

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 12:00

PC Open Date & Time

31 AUG 2020 11:45

PC Close Date & Time

31 AUG 2020 14:15

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

2

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

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 00:05

PC Open Date & Time

31 AUG 2020 15:10

PC Close Date & Time

01 SEP 2020 11:59



US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:25:56

**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

01 SEP 2020 22:59

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:25:56

**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

03 SEP 2020 00:03

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:25:56

**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

03 SEP 2020 23:39

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:25:56

**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

04 SEP 2020 22:56

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:25:56

**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

05 SEP 2020 23:14

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:25:56

**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

06 SEP 2020 23:10

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:25:56

**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 ☐

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:25:56

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 12:02
PC Open Date & Time	31 AUG 2020 11:45
PC Close Date & Time	31 AUG 2020 14:15



US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:25:56

**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 ☐

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:25:56

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 00:04
PC Open Date & Time	31 AUG 2020 15:10
PC Close Date & Time	01 SEP 2020 11:59

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:25:56

**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 ☒

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:25:56

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 23:01
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:25:56

**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 ☒

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:25:56

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 00:04
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:25:56

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:25:56

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 23:40
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59



US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:25:56

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 ☒

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:25:56

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 22:57
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:25:56

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 ☒

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:25:56

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 23:15
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:25:56

**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 ☒

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:25:56

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 23:11
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3672278

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:08:44

Generated On: 10 Jun 2021 09:25:56

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*

US3672278

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:08:44

Generated On: 10 Jun 2021 09:25:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3672278

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:08:44

Generated On: 10 Jun 2021 09:25:56

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3672278

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:08:44

Generated On: 10 Jun 2021 09:25:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672278

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:08:44

Generated On: 10 Jun 2021 09:25:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3672278

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:08:44

Generated On: 10 Jun 2021 09:25:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672278

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 20:08:44

Generated On: 10 Jun 2021 09:25:56

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

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 20:08:44

Generated On: 10 Jun 2021 09:25:56

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 SEP 2020
Time of assessment (00:00-23:59)	10:16 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 10:16
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)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 20:08:44

Generated On: 10 Jun 2021 09:25:56

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

US3672278

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 20:08:44

Generated On: 10 Jun 2021 09:25:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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



US3672278

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 20:08:44

Generated On: 10 Jun 2021 09:25:56

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?

What was the treatment date? (dd MMM yyyy)

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

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3672278

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 20:08:44

Generated On: 10 Jun 2021 09:25:56

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 SEP 2020

Collection time (00:00-23:59)

10:43 (24 HR)

Collection date and time (derived)

28 SEP 2020 10:43

US3672278

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 20:08:44

Generated On: 10 Jun 2021 09:25:56

Collection date (dd MMM yyyy)			28 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:30	28 SEP 2020 10:30
Nasopharyngeal Swab 2	No		

US3672278

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:08:44

Generated On: 10 Jun 2021 09:25:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672278

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:08:44

Generated On: 10 Jun 2021 09:25:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3672278

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:08:44

Generated On: 10 Jun 2021 09:25:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672278

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:08:44

Generated On: 10 Jun 2021 09:25:56

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*

US3672278

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:08:44

Generated On: 10 Jun 2021 09:25:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3672278

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 20:08:44

Generated On: 10 Jun 2021 09:25:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3672278

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:08:44

Generated On: 10 Jun 2021 09:25:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672278

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 20:08:44

Generated On: 10 Jun 2021 09:25:56

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

US3672278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 20:08:44

Generated On: 10 Jun 2021 09:25:56

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 OCT 2020
Time of assessment (00:00-23:59)	10:07 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 10:07
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)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	97 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	54 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3672278

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 20:08:44

Generated On: 10 Jun 2021 09:25:56

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.*

US3672278

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 20:08:44

Generated On: 10 Jun 2021 09:25:56

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 OCT 2020

Collection time (00:00-23:59)

10:15 (24 HR)

Collection date and time (derived)

23 OCT 2020 10:15

US3672278

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 20:08:44

Generated On: 10 Jun 2021 09:25:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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

31 OCT 2020 19:04:00

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59



US3672278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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

07 NOV 2020 18:09:54

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3672278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 NOV 2020 23:29:50
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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18 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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22 NOV 2020 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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25 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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29 NOV 2020 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

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	04 DEC 2020 22:16:26
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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

12 DEC 2020 00:37:47

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59



US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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

16 DEC 2020 22:33:00

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 DEC 2020 00:02:48

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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

30 DEC 2020 21:37:59

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 JAN 2021 22:19:30

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 JAN 2021 17:49:31

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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

20 JAN 2021 15:29:29

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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

28 JAN 2021 13:54:04

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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

07 FEB 2021 22:50:24

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59



US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 FEB 2021 14:33:26

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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

27 FEB 2021 23:30:24

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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

04 MAR 2021 15:17:36

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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

11 MAR 2021 20:14:13

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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

17 MAR 2021 21:42:55

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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

24 MAR 2021 13:05:25

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59



US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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

31 MAR 2021 15:56:59

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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

07 APR 2021 08:27:27

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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

14 APR 2021 16:46:45

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

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 <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"/>

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 APR 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 APR 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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

30 APR 2021 22:14:57

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

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

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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05 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAY 2021 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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12 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAY 2021 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

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

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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19 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAY 2021 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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 ☐ 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 ☐

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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26 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAY 2021 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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 ☐

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59



US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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 ☐ 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 ☐

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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16 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 JUN 2021 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

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

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

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 JUN 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

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

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

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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 ☐

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

DAY 320

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

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

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

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

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

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

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

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

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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14 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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18 JUL 2021 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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 ☐

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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 ☐  
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 ☐

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59



US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

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"/>

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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04 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 AUG 2021 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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11 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 AUG 2021 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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 ☐

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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18 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 AUG 2021 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 AUG 2021 23:59



US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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 ☐

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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01 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 SEP 2021 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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 ☐

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	08 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 SEP 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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 ☐

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

15 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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 ☐

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59



US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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 ☐

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

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"/>

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

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"/>

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

13 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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 ☐ 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 ☐

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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20 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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24 OCT 2021 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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27 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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31 OCT 2021 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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 ☐

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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°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 ☐

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

10 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

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

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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17 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 NOV 2021 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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 ☐

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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24 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 NOV 2021 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

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"/>

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 DEC 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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 ☐

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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08 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 DEC 2021 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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 ☐

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 DEC 2021 23:59



US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 DEC 2021 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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 ☐ 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 ☐

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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29 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 JAN 2022 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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05 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 JAN 2022 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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12 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 JAN 2022 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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 ☐

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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26 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 JAN 2022 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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 ☐ 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 ☐

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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09 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 FEB 2022 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

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

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

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 FEB 2022 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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 ☐

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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 ☐

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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09 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 MAR 2022 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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 ☐

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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 ☐

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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23 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAR 2022 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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 ☐

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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30 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 APR 2022 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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 ☐

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59



US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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 ☐

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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13 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 APR 2022 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

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"/>

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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20 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 APR 2022 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

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

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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27 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 MAY 2022 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

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"/>

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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04 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 MAY 2022 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

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

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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11 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 MAY 2022 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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 ☐

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

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

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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25 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 MAY 2022 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

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

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59



US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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 ☐

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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 ☐

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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22 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 JUN 2022 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

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"/>

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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29 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 JUL 2022 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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 ☐

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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06 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 JUL 2022 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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 ☐

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 JUL 2022 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

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"/>

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

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

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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27 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 JUL 2022 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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 ☐

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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03 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 AUG 2022 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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 ☐

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	10 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	14 AUG 2022 23:59
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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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 ☐

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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17 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 AUG 2022 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

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"/>

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59



US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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31 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 SEP 2022 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

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

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

DAY 747

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

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

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

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

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

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

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 ☐

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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 ☐

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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21 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 SEP 2022 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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28 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 OCT 2022 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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 ☐  
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 ☐

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

05 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**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 ☐

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

12 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 OCT 2022 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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19 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 OCT 2022 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

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26 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 OCT 2022 23:59

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US3672278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

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

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

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[Patient Cloud Open Date & Time](#)

02 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 NOV 2022 23:59

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**US3672278**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 10 Jun 2021 09:25:56**

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		27 FEB 2021 23:30:53

US3672278

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:05:45

Generated On: 10 Jun 2021 09:25:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3672278

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:05:45

Generated On: 10 Jun 2021 09:25:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672278

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:05:45

Generated On: 10 Jun 2021 09:25:56

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 DEC 2020

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

Comments

*If Contact Not Made, please provide Comments*



US3672278

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:05:45

Generated On: 10 Jun 2021 09:25:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672278

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 15:17:21

Generated On: 10 Jun 2021 09:25:56

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*

US3672278

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 15:17:21

Generated On: 10 Jun 2021 09:25:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672278

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:05:45

Generated On: 10 Jun 2021 09:25:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3672278

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:05:45

Generated On: 10 Jun 2021 09:25:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672278

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 15:17:21

Generated On: 10 Jun 2021 09:25:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3672278

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 15:17:21

Generated On: 10 Jun 2021 09:25:56

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) \_\_\_\_\_

US3672278

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 15:17:21

Generated On: 10 Jun 2021 09:25:56

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.*



US3672278

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 15:17:21

Generated On: 10 Jun 2021 09:25:56

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 MAR 2021

Collection time (00:00-23:59)

14:25 (24 HR)

Collection date and time (derived)

24 MAR 2021 14:25

US3672278

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 15:17:21

Generated On: 10 Jun 2021 09:25:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3672278**

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

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:25:56**

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*

**US3672278**

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

**Form: Continuing**

**Generated On: 10 Jun 2021 09:25:56**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3672278**

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

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:25:56**

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"/>

**US3672278**

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

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

**Generated On: 10 Jun 2021 09:25:56**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3672278

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

Form: Visit Date

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

Generated On: 10 Jun 2021 09:25:56

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

Visit date (dd MMM yyyy)	26 JAN 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3672278

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 15:17:21

Generated On: 10 Jun 2021 09:25:56

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



US3672278

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

Form: Vital Signs - Dosing

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

Generated On: 10 Jun 2021 09:25:56

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

US3672278

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

Form: Vital Signs - Dosing (1)

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

Generated On: 10 Jun 2021 09:25:56

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 JAN 2021
Time of assessment (00:00-23:59)	12:00 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 12:00
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	59 mmHg
Diastolic Blood Pressure units	MMHG

US3672278

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

Form: Vital Signs - Dosing (2)

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

Generated On: 10 Jun 2021 09:25:56

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 JAN 2021
Time of assessment (00:00-23:59)	12:56 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 12:56
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3672278

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

Form: Physical Examination

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

Generated On: 10 Jun 2021 09:25:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 JAN 2021

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

US3672278

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

Form: Exposure

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

Generated On: 10 Jun 2021 09:25:56

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

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

What was the treatment time? (00:00-23:59) 12:22 (24 HR)

Treatment Date and Time (derived) 26 JAN 2021 12:22

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

US3672278

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

Form: Immunogenicity Assessment

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

Generated On: 10 Jun 2021 09:25:56

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 JAN 2021

Collection time (00:00-23:59)

12:09 (24 HR)

Collection date and time (derived)

26 JAN 2021 12:09

US3672278

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

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

Generated On: 10 Jun 2021 09:25:56

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 JAN 2021
Collection time (00:00 - 23:59)	11:55
Collection Date and Time (derived)	26 JAN 2021 11:55

US3672278

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

Form: Continuing

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

Generated On: 10 Jun 2021 09:25:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3672278

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 18:05:45

Generated On: 10 Jun 2021 09:25:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3672278

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 18:05:45

Generated On: 10 Jun 2021 09:25:56

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

US3672278

Folder: OL-D29 (1)

Form: Visit Date

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

Generated On: 10 Jun 2021 09:25:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 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

US3672278

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

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

Generated On: 10 Jun 2021 09:25:56

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 FEB 2021
Time of assessment (00:00-23:59)	10:44 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 10:44
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)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	57 mmHg
Diastolic Blood Pressure units	MMHG

US3672278

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

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

Generated On: 10 Jun 2021 09:25:56

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)	24 FEB 2021
Time of assessment (00:00-23:59)	11:48 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 11:48
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	59 mmHg
Diastolic Blood Pressure units	MMHG

US3672278

Folder: OL-D29 (1)

Form: Physical Examination

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

Generated On: 10 Jun 2021 09:25:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 FEB 2021

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

US3672278

Folder: OL-D29 (1)

Form: Exposure

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

Generated On: 10 Jun 2021 09:25:56

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) 24 FEB 2021

What was the treatment time? (00:00-23:59) 11:10 (24 HR)

Treatment Date and Time (derived) 24 FEB 2021 11:10

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

What was the frequency of the study treatment dosing? ONCE

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

US3672278

Folder: OL-D29 (1)

Form: Continuing

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

Generated On: 10 Jun 2021 09:25:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3672278

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 15:17:21

Generated On: 10 Jun 2021 09:25:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3672278

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 15:17:21

Generated On: 10 Jun 2021 09:25:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3672278

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 15:17:21

Generated On: 10 Jun 2021 09:25:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3672278

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 15:17:21

Generated On: 10 Jun 2021 09:25:56

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	24 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	14:11 (24 HR)
Vital Signs Date and Time (derived)	24 MAR 2021 14:11
Temperature ( <i>xxx.x</i> )	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	72 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3672278

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 15:17:21

Generated On: 10 Jun 2021 09:25:56

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.*

US3672278

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 15:17:21

Generated On: 10 Jun 2021 09:25:56

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 MAR 2021
Collection time (00:00-23:59)	14:25 (24 HR)
Collection date and time (derived)	24 MAR 2021 14:25

US3672278

Folder: Adverse Events

Form: Adverse Events Summary

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

Generated On: 10 Jun 2021 09:25:56

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3672278

Folder: Adverse Events

Form: Adverse Events (1)

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

Generated On: 10 Jun 2021 09:25:56

AEID	USA-US116-2020-MRNA-1273-P30 1000001
Adverse event	ISCHEMIC STROKE (FRONTAL LOBE)
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)	10 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	11 SEP 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 type="radio"/> Grade 4 <input checked="" 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)	10 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	11 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (1)

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

Generated On: 10 Jun 2021 09:25:56

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	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 checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	AE OF SPEECH DEFICIT
Narrative	

US3672278

Folder: Adverse Events

Form: Adverse Events (1)

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

Generated On: 10 Jun 2021 09:25:56

SUBJECT IS A 78 YEAR OLD  
MAKE WITH HISTORY OF CVD,  
CAD, CHF, AND DM. DAY 8  
PHONE CALL WAS MADE ON  
9/11/2020 AND WAS MOSTLY  
COMPLETED WITH SUBJECT'S  
WIFE. SUBJECT'S WIFE  
REPORTS ON 9/10/2020. SUBJECT  
DEVELOPED INABILITY TO  
SPEAK. HE WAS ADMITTED TO  
THE HOSPITAL AND  
DIAGNOSED WITH FRONTAL  
LOBE STROKE. SUBJECT WAS  
DISCHARGED 9/11/2020 WITH  
ONGOING SPEECH DEFICIT. HE  
WAS STARTED ON PLAVIX AND  
WILL BE STARTING SPEECH  
THERAPY. MEDICAL RECORDS  
WERE RECEIVED WHICH  
INCLUDED LAB RESULTS AND  
DIAGNOSTIC TEST RESULTS.  
RELEVANT OR ABNORMAL  
LAB TESTS INCLUDE: PTT 28.7  
SEC, PT 13.4 SEC, INR 1.0,  
HGA1C 7.7%. FINDINGS FROM  
NONCONTRAST BRAIN CT  
SCAN ON 09/10/20 @ 1538  
INLCUDE SMALL EVOLVING  
ACUTE INFARCTIONS IN THE  
LEFT INSULAR CORTEX AND  
ANTERIOR LEFT CORONA  
RADIATA, AND NO  
HEMORRHAGE. ULTRASOUND  
CAROTID DUPLEX BILATERAL  
COMPLETED ON 09/10/20 @ 1840  
SHOWED NO STENOSIS  
BILATERALLY.

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) 05 Mar 2021 18:05:44

Generated On: 10 Jun 2021 09:25:56

AEID	USA-US116-2020-MRNA-1273-P30 1000001
Adverse event	SPEECH DEFICIT
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)	10 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	26 JAN 2021
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 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)	10 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	11 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (2)

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

Generated On: 10 Jun 2021 09:25:56

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

US3672278

Folder: Adverse Events

Form: Adverse Events (2)

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

Generated On: 10 Jun 2021 09:25:56

SUBJECT IS A 78 YEAR OLD  
MAKE WITH HISTORY OF CVD,  
CAD, CHF, AND DM. DAY 8  
PHONE CALL WAS MADE ON  
9/11/2020 AND WAS MOSTLY  
COMPLETED WITH SUBJECT'S  
WIFE. SUBJECT'S WIFE  
REPORTS ON 9/10/2020. SUBJECT  
DEVELOPED INABILITY TO  
SPEAK. HE WAS ADMITTED TO  
THE HOSPITAL AND  
DIAGNOSED WITH FRONTAL  
LOBE STROKE. SUBJECT WAS  
DISCHARGED 9/11/2020 WITH  
ONGOING SPEECH DEFICIT. HE  
WAS STARTED ON PLAVIX AND  
WILL BE STARTING SPEECH  
THERAPY. MEDICAL RECORDS  
WERE RECEIVED WHICH  
INCLUDED LAB RESULTS AND  
DIAGNOSTIC TEST RESULTS.  
RELEVANT OR ABNORMAL  
LAB TESTS INCLUDE: PTT 28.7  
SEC, PT 13.4 SEC, INR 1.0,  
HGA1C 7.7%. FINDINGS FROM  
NONCONTRAST BRAIN CT  
SCAN ON 09/10/20 @ 1538  
INLCUDE SMALL EVOLVING  
ACUTE INFARCTIONS IN THE  
LEFT INSULAR CORTEX AND  
ANTERIOR LEFT CORONA  
RADIATA, AND NO  
HEMORRHAGE. ULTRASOUND  
CAROTID DUPLEX BILATERAL  
COMPLETED ON 09/10/20 @ 1840  
SHOWED NO STENOSIS  
BILATERALLY.

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

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

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

Generated On: 10 Jun 2021 09:25:56

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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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US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 21:43:18

Generated On: 10 Jun 2021 09:25:56

Name of Medication METOPROLOL

Prophylaxis Yes ☐  
No ☒

Indication MYOCARDIAL INFARCTION

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 21:43:18

Generated On: 10 Jun 2021 09:25:56

	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 1989
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 (2)

Data signed: (b) (4) 08 Apr 2021 21:43:18

Generated On: 10 Jun 2021 09:25:56

Name of Medication LORATADINE

Prophylaxis Yes ☐  
No ☒

Indication ALLERGIC RHINITIS

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 21:43:18

Generated On: 10 Jun 2021 09:25:56

	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 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 21:43:18

Generated On: 10 Jun 2021 09:25:56

Name of Medication BENADRYL

Prophylaxis Yes ☐  
No ☒

Indication LEG CRAMPS (BILATERAL)

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 21:43:18

Generated On: 10 Jun 2021 09:25:56

	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 1990
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 21:43:18

Generated On: 10 Jun 2021 09:25:56

Name of Medication SPIRNOLACTONE

Prophylaxis Yes ☐  
No ☒

Indication MYOCARDIAL INFARCTION

Dose per administration 12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 21:43:18

Generated On: 10 Jun 2021 09:25:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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) 08 Apr 2021 21:43:18

Generated On: 10 Jun 2021 09:25:56

Name of Medication GLIPIZIDE

Prophylaxis Yes ☐  
No ☒

Indication TYPE II DIABETES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 21:43:18

Generated On: 10 Jun 2021 09:25:56

	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 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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) 08 Apr 2021 21:43:18

Generated On: 10 Jun 2021 09:25:56

Name of Medication LOSARTAN

Prophylaxis Yes ☐  
No ☒

Indication MYOCARDIAL INFARCTION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 21:43:18

Generated On: 10 Jun 2021 09:25:56

	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 1989	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	10 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 (8)

Data signed: (b) (4) 08 Apr 2021 21:43:18

Generated On: 10 Jun 2021 09:25:56

Name of Medication LASIX

Prophylaxis Yes ☐  
No ☒

Indication MYCARDIAL INFARCTION

Dose per administration 20

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 (8)

Data signed: (b) (4) 08 Apr 2021 21:43:18

Generated On: 10 Jun 2021 09:25:56

	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 1989
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"/>

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 21:43:18

Generated On: 10 Jun 2021 09:25:56

Name of Medication	METFORMIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	TYPE 2 DM
Dose per administration	500
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input checked="" type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input checked="" type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 21:43:18

Generated On: 10 Jun 2021 09:25:56

	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 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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 (10)

Data signed: (b) (4) 08 Apr 2021 21:43:18

Generated On: 10 Jun 2021 09:25:56

Name of Medication PLAVIX

Prophylaxis Yes ☐  
No ☒

Indication FRONTAL LOBE STROKE

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 21:43:18

Generated On: 10 Jun 2021 09:25:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 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)		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 (11)

Data signed: (b) (4) 08 Apr 2021 21:43:18

Generated On: 10 Jun 2021 09:25:56

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☐  
No ☒

Indication INFLUENZA PROPHYLAXIS

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 21:43:18

Generated On: 10 Jun 2021 09:25:56

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	IM	
Start date (dd MMM yyyy)	04 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	04 OCT 2020	
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"/>

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 21:43:18

Generated On: 10 Jun 2021 09:25:56

Name of Medication LOSARTAN

Prophylaxis Yes ☒  
No ☐

Indication MYOCARDIAL INFARCTION  
(PREVENTION)

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 21:43:18

Generated On: 10 Jun 2021 09:25:56

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 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)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 21:43:18

Generated On: 10 Jun 2021 09:25:56

Name of Medication ASPIRIN

Prophylaxis Yes ☐  
No ☒

Indication FRONTAL LOBE STROKE

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 21:43:18

Generated On: 10 Jun 2021 09:25:56

	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)		10 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 10 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 21:43:18

Generated On: 10 Jun 2021 09:25:56

Name of Medication DIPHENHYDRAMINE

Prophylaxis Yes ☐  
No ☒

Indication OBSTRUCTIVE SLEEP APNEA

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 21:43:18

Generated On: 10 Jun 2021 09:25:56

	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)		10 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)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Apr 2021 21:43:18

Generated On: 10 Jun 2021 09:25:56

Name of Medication PRAVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication FRONTAL LOBE STROKE

Dose per administration 80

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 (15)

Data signed: (b) (4) 08 Apr 2021 21:43:18

Generated On: 10 Jun 2021 09:25:56

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 08 Apr 2021 21:43:18

Generated On: 10 Jun 2021 09:25:56

Name of Medication METFORMIN

Prophylaxis Yes ☐  
No ☒

Indication TYPE 2 DIABETES

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 (16)

Data signed: (b) (4) 08 Apr 2021 21:43:18

Generated On: 10 Jun 2021 09:25:56

	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 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"/>

US3672278

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

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

Generated On: 10 Jun 2021 09:25:56

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3672278

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 14 Apr 2021 20:20:01

Generated On: 10 Jun 2021 09:25:56

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
10 SEP 2020	CT HEAD STROKE PROTOCOL W/O CONTRAST	Adverse Event	
10 SEP 2020	CAROTID DUPLEX	Adverse Event	
10 SEP 2020	SPEECH THERAPY	Adverse Event	
10 SEP 2020	DIAGNOSTIC LAB TESTING	Adverse Event	

US3672278

Folder: End of Study (1)

Form: Dosing Discontinuation

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

Generated On: 10 Jun 2021 09:25:56

---

Date of dosing discontinuation (dd MMM yyyy) 28 SEP 2020

---

Primary reason for dosing discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input checked="" type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Due to SARS-COV-2	<input type="checkbox"/>
Other	<input type="checkbox"/>

---

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify AE#1

---

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:25:56

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 ☐



US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 05 Mar 2021 18:05:45

Generated On: 10 Jun 2021 09:25:56

SAEID	USA-US116-2020-MRNA-1273-P301000001
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 checked="" type="radio"/> No <input 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)	7

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 05 Mar 2021 18:05:45

Generated On: 10 Jun 2021 09:25:56

SAEID	USA-US116-2020-MRNA-1273-P301000001
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 checked="" type="radio"/> No <input 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)	7
Date of submission (Pre-filled from custom function)	12/SEP/2020 15:21
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

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 05 Mar 2021 18:05:45

Generated On: 10 Jun 2021 09:25:56

SAEID	USA-US116-2020-MRNA-1273-P301000001
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 checked="" type="radio"/> No <input 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)	7
Date of submission (Pre-filled from custom function)	23/OCT/2020 16:30
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

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 05 Mar 2021 18:05:45

Generated On: 10 Jun 2021 09:25:56

SAEID	USA-US116-2020-MRNA-1273-P301000001
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 checked="" type="radio"/> No <input 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)	7
Date of submission (Pre-filled from custom function)	28/OCT/2020 15:04
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

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Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 05 Mar 2021 18:05:45

Generated On: 10 Jun 2021 09:25:56

SAEID	USA-US116-2020-MRNA-1273-P301000001
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 checked="" type="radio"/> No <input 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)	7
Date of submission (Pre-filled from custom function)	02/NOV/2020 17:16
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

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 05 Mar 2021 18:05:45

Generated On: 10 Jun 2021 09:25:56

SAEID	USA-US116-2020-MRNA-1273-P301000001
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 checked="" type="radio"/> No <input 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)	7
Date of submission (Pre-filled from custom function)	12/NOV/2020 18:16
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

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Data signed: (b) (4) 05 Mar 2021 18:05:45

Generated On: 10 Jun 2021 09:25:56

SAEID	USA-US116-2020-MRNA-1273-P301000001
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 checked="" type="radio"/> No <input 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)	7
Date of submission (Pre-filled from custom function)	25/NOV/2020 14:47
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

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Data signed: (b) (4) 05 Mar 2021 18:05:45

Generated On: 10 Jun 2021 09:25:56

SAEID	USA-US116-2020-MRNA-1273-P301000001
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 checked="" type="radio"/> No <input 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)	7
Date of submission (Pre-filled from custom function)	25/FEB/2021 12:01
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

US3672278 (Prod: Coastal Carolina Research Center)

**US3672278**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:25:56**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 12:12:46
User entered 'US3672278'	RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 18:09:22

**US3672278**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:25:56**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:12:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 18:41:59

**US3672278**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:12:51
User entered '24 AUG 2020'	RWS_ENDPOINT	24 Aug 2020 18:09:23
	ENDPOINT (b) (4)	

**US3672278**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:12:51
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	25 Aug 2020 18:41:59

**US3672278**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:25:56**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered 'SCRN'	System	25 Aug 2020 18:41:59

**US3672278**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:13:10
User entered (b) (6) 1942'	RWS_ENDPOINT	24 Aug 2020 18:09:24
	ENDPOINT (b) (4)	

**US3672278**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:25:56**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:13:10
User entered '78'	(b) (4), (b) (6)	25 Aug 2020 18:42:18



**US3672278**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:25:56**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered 'YEARS'	System	25 Aug 2020 18:42:18

**US3672278**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:25:56**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered '78'	System	25 Aug 2020 18:44:05

**US3672278**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:25:56**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:13:10
User entered 'Male (M)'	(b) (4), (b) (6)	25 Aug 2020 18:42:18

**US3672278**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:25:56**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:13:10
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	25 Aug 2020 18:42:18

**US3672278**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:25:56**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:13:10
User entered 'l'	(b) (4), (b) (6)	25 Aug 2020 18:42:18

**US3672278**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:25:56**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:13:10
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:42:18

**US3672278**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:25:56**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:13:10
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:42:18

**US3672278**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:25:56**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:13:10
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:42:18



**US3672278**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:25:56**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:13:10
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:42:18

**US3672278**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:25:56**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:13:10
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:42:18

**US3672278**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:25:56**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:13:10
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 18:42:18

**US3672278**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:25:56**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:13:10
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:42:18

**US3672278**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:25:56**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:13:10
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:42:18

**US3672278**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:13:32
User entered '24 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 18:44:05

**US3672278**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered 'Aug 2020'	System	25 Aug 2020 18:44:05

**US3672278**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered '2020'	System	25 Aug 2020 18:44:05



**US3672278**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:25:56**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:13:32
User entered 'Amendment 2 (2)' reason for change:	(b) (4), (b) (6)	25 Aug 2020 18:47:29
Data Entry Error		
User entered 'Amendment 1 (1)'	(b) (4), (b) (6)	25 Aug 2020 18:44:05

**US3672278**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:13:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 18:44:05

**US3672278**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:13:32
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 18:44:05

**US3672278**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:25:56**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:13:32
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 18:44:05

**US3672278**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:25:56**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:13:32
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 18:44:05

**US3672278**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:25:56**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:13:32
User entered empty.	RWS_ENDPOINT	24 Aug 2020 18:09:23
	ENDPOINT (b) (4)	

**US3672278**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:25:56**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered 'I'	System	25 Aug 2020 18:44:20

**US3672278**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:15:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 18:44:20



US3672278

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:25:56

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User closed query 'Please update MH page. Thanks' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 16:02:46
Query 'Please update MH page. Thanks' answered with 'Updated' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 16:02:16
User opened query 'Please update MH page. Thanks' (Site from CRA).	(b) (4), (b) (6)	22 Sep 2020 12:20:04
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:15:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 18:47:13

US3672278

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:25:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User closed query 'Please update page per Med Hx report. Thanks' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 15:54:55
Query 'Please update page per Med Hx report. Thanks' answered with 'Updated per source.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 18:34:10
User opened query 'Please update page per Med Hx report. Thanks' (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 13:59:16
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 18:49:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 18:49:31
Data point term sent to Coder	System	25 Aug 2020 18:49:06
User entered 'Myocardial infarction'	(b) (4), (b) (6)	25 Aug 2020 18:48:12

**US3672278**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered 'un UNK 1989'	(b) (4), (b) (6)	25 Aug 2020 18:48:12

**US3672278**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:48:12

US3672278

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:25:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:54:44
User closed query 'Per source, this is not ongoing. End date is UN/UNK/1989. Please verify and update. Thanks!' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 15:54:41
Query 'Per source, this is not ongoing. End date is UN/UNK/1989. Please verify and update. Thanks!' answered with 'Updated per source' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 18:33:57
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 18:33:30
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 18:33:30
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User opened query 'Per source, this is not ongoing. End date is UN/UNK/1989. Please verify and update. Thanks!' (Site from CRA).	(b) (4), (b) (6)	22 Sep 2020 12:16:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 18:48:12

US3672278

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:25:56

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User closed query 'Per MM, please provide the end date ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 18:35:34
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 15:54:39
Query 'Per MM, please provide the end date ' answered with 'Updated per source.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 18:34:03
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 18:33:30
User entered 'un UNK 1989' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 18:33:30
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User opened query 'Per MM, please provide the end date ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 19:53:50
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 18:48:12

**US3672278**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:48:12

**US3672278**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered 'Jan 1989'	System	25 Aug 2020 18:48:12



**US3672278**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered '1989'	System	25 Aug 2020 18:48:12

**US3672278**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered 'Jan 1989'	System	21 Oct 2020 18:33:30
User entered empty.	System	25 Aug 2020 18:48:12

**US3672278**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered '1989'	System	21 Oct 2020 18:33:30
User entered empty.	System	25 Aug 2020 18:48:12

US3672278

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:25:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 12:16:49
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) (b) (4)	25 Aug 2020 18:52:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 18:52:39
Data point term sent to Coder	System	25 Aug 2020 18:51:13
User entered 'Type 2 Diabetes'	(b) (4), (b) (6)	25 Aug 2020 18:50:23

**US3672278**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered 'un UNK 2014'	(b) (4), (b) (6)	25 Aug 2020 18:50:23

**US3672278**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:25:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:50:23

**US3672278**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:25:56**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 18:50:23

**US3672278**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 18:50:23



**US3672278**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:25:56**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:50:23

**US3672278**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered 'Jan 2014'	System	25 Aug 2020 18:50:23

**US3672278**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered '2014'	System	25 Aug 2020 18:50:23

**US3672278**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered empty.	System	25 Aug 2020 18:50:23

**US3672278**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered empty.	System	25 Aug 2020 18:50:23

US3672278

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:25:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 12:16:49
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Leg cramps - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 18:52:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 18:52:39
Data point term sent to Coder	System	25 Aug 2020 18:51:15
User entered 'Leg cramps'	(b) (4), (b) (6)	25 Aug 2020 18:50:40

**US3672278**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered 'un UNK 1990'	(b) (4), (b) (6)	25 Aug 2020 18:50:40

**US3672278**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:25:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:50:40



**US3672278**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:25:56**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 18:50:40

**US3672278**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 18:50:40

**US3672278**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:25:56**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:50:40

**US3672278**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered 'Jan 1990'	System	25 Aug 2020 18:50:40

**US3672278**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered '1990'	System	25 Aug 2020 18:50:40

**US3672278**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered empty.	System	25 Aug 2020 18:50:40

**US3672278**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered empty.	System	25 Aug 2020 18:50:40

US3672278

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:25:56

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 12:16:49
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Rhinitis allergic, LLT: Allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 18:52:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 18:52:39
Data point term sent to Coder	System	25 Aug 2020 18:51:13
User entered 'allergic rhinitis'	(b) (4), (b) (6)	25 Aug 2020 18:50:54



**US3672278**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered 'un UNK 1989'	(b) (4), (b) (6)	25 Aug 2020 18:50:54

**US3672278**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:25:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:50:54

**US3672278**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:25:56**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 18:50:54

**US3672278**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 18:50:54

**US3672278**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:25:56**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:50:54

**US3672278**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered 'Jan 1989'	System	25 Aug 2020 18:50:54

**US3672278**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered '1989'	System	25 Aug 2020 18:50:54

**US3672278**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered empty.	System	25 Aug 2020 18:50:54



**US3672278**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered empty.	System	25 Aug 2020 18:50:54

US3672278

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:25:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User closed query 'Per MM: Please include the underlying condition that led to the procedure. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 18:37:10
Query 'Per MM: Please include the underlying condition that led to the procedure. ' answered with 'Underlying Condition listed in MH' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 16:07:58
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User opened query 'Per MM: Please include the underlying condition that led to the procedure. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 19:55:07
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac device therapeutic procedures, PT: Implantable defibrillator insertion, LLT: Implantable defibrillator insertion - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 18:55:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 18:55:33
Data point term sent to Coder	System	25 Aug 2020 18:54:26
User entered 'DEFIBRILLATOR IMPLANT' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 18:54:11
Data point term sent to Coder	System	25 Aug 2020 18:52:18
User entered 'defibrillator inimplant'	(b) (4), (b) (6)	25 Aug 2020 18:51:24

**US3672278**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered 'un Dec 2019'	(b) (4), (b) (6)	25 Aug 2020 18:51:24

**US3672278**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:25:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:51:24

**US3672278**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:25:56**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 18:51:24

**US3672278**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 18:51:24

**US3672278**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:25:56**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:51:24

**US3672278**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered 'Dec 2019'	System	25 Aug 2020 18:51:24



**US3672278**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered '2019'	System	25 Aug 2020 18:51:24

**US3672278**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered empty.	System	25 Aug 2020 18:51:24

**US3672278**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered empty.	System	25 Aug 2020 18:51:24

US3672278

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:25:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 12:16:49
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 18:53:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 18:53:42
Data point term sent to Coder	System	25 Aug 2020 18:52:19
User entered 'coronary artery disease'	(b) (4), (b) (6)	25 Aug 2020 18:51:53

**US3672278**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered 'un Dec 2019'	(b) (4), (b) (6)	25 Aug 2020 18:51:53

**US3672278**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:25:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:51:53

**US3672278**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:25:56**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 18:51:53

**US3672278**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 18:51:53



**US3672278**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:25:56**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:51:53

**US3672278**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered 'Dec 2019'	System	25 Aug 2020 18:51:53

**US3672278**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered '2019'	System	25 Aug 2020 18:51:53

**US3672278**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered empty.	System	25 Aug 2020 18:51:53

**US3672278**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered empty.	System	25 Aug 2020 18:51:53

US3672278

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:25:56

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User closed query 'Per DM CLR: Please review if corresponding medication is given. Note that there is no Concomitant Medication listed and treatment is typically required for this condition. Reconcile and update as appropriate or comment. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 18:40:48
Query 'Per DM CLR: Please review if corresponding medication is given. Note that there is no Concomitant Medication listed and treatment is typically required for this condition. Reconcile and update as appropriate or comment. ' answered with 'all conmeds are up to date' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 16:54:06
User opened query 'Per DM CLR: Please review if corresponding medication is given. Note that there is no Concomitant Medication listed and treatment is typically required for this condition. Reconcile and update as appropriate or comment. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 06:52:17
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 18:55:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	25 Aug 2020 18:55:55
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\\23.0.	Coder Import (b) (4)	25 Aug 2020 18:55:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	25 Aug 2020 18:55:34
Data point term sent to Coder	System	25 Aug 2020 18:54:25
User entered 'congestive heart failure'	(b) (4), (b) (6)	25 Aug 2020 18:53:26

**US3672278**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered 'un Dec 2019'	(b) (4), (b) (6)	25 Aug 2020 18:53:26

**US3672278**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:25:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:53:26



**US3672278**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:25:56**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 18:53:26

**US3672278**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 18:53:26

**US3672278**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:25:56**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:16:49
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:53:26

**US3672278**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered 'Dec 2019'	System	25 Aug 2020 18:53:26

**US3672278**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered '2019'	System	25 Aug 2020 18:53:26

**US3672278**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered empty.	System	25 Aug 2020 18:53:26

**US3672278**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered empty.	System	25 Aug 2020 18:53:26

US3672278

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:25:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:00:00
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system vascular disorders NEC, PT: Cerebrovascular disorder, LLT: Cerebrovascular disorder - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 06:09:55
Data point term sent to Coder	(b) (4)	
User entered 'cerebral vascular disease'	System	28 Sep 2020 20:22:13
	(b) (4), (b) (6)	28 Sep 2020 20:21:55



**US3672278**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:00:00
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered 'un UNK 2002'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 20:21:55

**US3672278**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:25:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:00:00
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 20:21:55

**US3672278**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:25:56**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:00:00
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 20:21:55

**US3672278**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:00:00
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:21:55

**US3672278**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:25:56**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:00:00
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 20:21:55

**US3672278**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered 'Jan 2002'	System	28 Sep 2020 20:21:55

**US3672278**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered '2002'	System	28 Sep 2020 20:21:55

**US3672278**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered empty.	System	28 Sep 2020 20:21:55



**US3672278**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered empty.	System	28 Sep 2020 20:21:55

US3672278

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:25:56

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:00:00
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Obstructive sleep apnea syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	19 Mar 2021 14:58:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Mar 2021 14:58:32
Data point term sent to Coder	System	19 Mar 2021 14:57:48
User entered 'obstructive sleep apnea'	(b) (4), (b) (6)	19 Mar 2021 14:57:06

**US3672278**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:00:00
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 14:57:06

**US3672278**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:25:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:00:00
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
User entered 'l'	(b) (4), (b) (6)	19 Mar 2021 14:57:06

**US3672278**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:25:56**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:00:00
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 14:57:06

**US3672278**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:00:00
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 14:57:06

**US3672278**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:25:56**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:00:00
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
User entered '0'	(b) (4), (b) (6)	19 Mar 2021 14:57:06

**US3672278**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered empty.	System	19 Mar 2021 14:57:06



**US3672278**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered empty.	System	19 Mar 2021 14:57:06

**US3672278**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered empty.	System	19 Mar 2021 14:57:06

**US3672278**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered empty.	System	19 Mar 2021 14:57:06

**US3672278**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:25:56**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:21:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 18:54:54

**US3672278**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:25:56**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:21:07
User entered '24 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 18:54:54

**US3672278**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:25:56**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:21:07
User entered '14:15'	(b) (4), (b) (6)	25 Aug 2020 18:54:54

**US3672278**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:25:56**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered '24 Aug 2020 14:15'	System	25 Aug 2020 18:54:54

US3672278

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:56

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:21:07
User entered '177.5' cm	(b) (4), (b) (6)	25 Aug 2020 18:54:54
DataPoint set to visible.	System	25 Aug 2020 18:44:20



**US3672278**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:25:56**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:21:07
User entered '95.2' kg	(b) (4), (b) (6)	25 Aug 2020 18:54:54
DataPoint set to visible.	System	25 Aug 2020 18:44:20

**US3672278**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:25:56**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
Amendment Manager: User entered '30.21623'	System	17 Sep 2020 00:21:38
User entered '30.2'	System	25 Aug 2020 18:54:54
DataPoint set to visible.	System	25 Aug 2020 18:44:20

**US3672278**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:25:56**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered 'kg/m2'	System	25 Aug 2020 18:54:54
DataPoint set to visible.	System	25 Aug 2020 18:44:20

US3672278

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:21:07
User entered '97.6' F reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:10:48
User entered missing code ND - Not Done.	(b) (4), (b) (6)	25 Aug 2020 18:54:54

**US3672278**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:25:56**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:21:07
User entered 'Other (Other)'	(b) (4), (b) (6)	25 Aug 2020 18:54:54

**US3672278**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:25:56**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:21:07
User entered missing code ND - Not Done.	(b) (4), (b) (6)	25 Aug 2020 18:54:54

**US3672278**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:25:56**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:21:07
User entered '72' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:10:48
User entered missing code ND - Not Done.	(b) (4), (b) (6)	25 Aug 2020 18:54:54

**US3672278**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:25:56**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered 'bpm'	System	25 Aug 2020 18:54:54



US3672278

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:21:07
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:10:48
User entered missing code ND - Not Done.	(b) (4), (b) (6)	25 Aug 2020 18:54:54

US3672278

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered 'breaths/min'	System	25 Aug 2020 18:54:54

US3672278

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:56

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:21:07
User entered '103' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:10:48
User entered missing code ND - Not Done.	(b) (4), (b) (6)	25 Aug 2020 18:54:54

US3672278

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered 'mmHg'	System	25 Aug 2020 18:54:54

**US3672278**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:25:56**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:21:07
User entered '67' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:10:48
User entered missing code ND - Not Done.	(b) (4), (b) (6)	25 Aug 2020 18:54:54

**US3672278**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:25:56**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User entered 'mmHg'	System	25 Aug 2020 18:54:54

US3672278

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:56

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02

**US3672278**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:25:56**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02



**US3672278**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:25:56**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:22:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 18:55:06

US3672278

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:25:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:22:08
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	07 Sep 2020 11:34:25
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		31 Aug 2020 15:03:39
User entered '24 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 18:55:06

US3672278

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:56

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:22:17
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 18:55:41

US3672278

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:56

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:22:17
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 18:55:41

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:56

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:22:17
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 18:55:41

US3672278

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:56

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:22:17
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 18:55:41

US3672278

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:56

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:22:17
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 18:55:41

US3672278

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:56

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:22:17
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 18:55:41



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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:56

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:22:17
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 18:55:41

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:56

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:22:17
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 18:55:41

US3672278

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:56

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:22:17
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 18:55:41

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:56

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:22:17
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 18:55:41

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:56

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:22:17
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 18:55:41

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:56

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:22:17
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 18:55:41

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:56

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:22:17
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 18:55:41

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:56

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:55:41



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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:56

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:22:17
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:55:41

US3672278

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:56

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:22:17
User entered 'I'	(b) (4), (b) (6)	25 Aug 2020 18:55:41

US3672278

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:56

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:22:17
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:55:41

US3672278

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:56

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:22:17
User entered '0'	(b) (4), (b) (6)	25 Aug 2020 18:55:41

US3672278

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:56

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:22:17
User entered 'l'	(b) (4), (b) (6)	25 Aug 2020 18:55:41

US3672278

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:56

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered 'I'	(b) (4), (b) (6)	25 Aug 2020 18:55:41

US3672278

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:25:56

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 18:04:02
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:22:17
User entered 'Resident in a community with ongoing person to person transmission.'	(b) (4), (b) (6)	25 Aug 2020 18:55:41

US3672278

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:25:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User closed query 'Please complete the immunogenicity assessment and Central Lab Swab page. Thanks!' (Site from CRA).	(b) (4)	
Query 'Please complete the immunogenicity assessment and Central Lab Swab page. Thanks!' answered with 'Completed.' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 15:55:56
User opened query 'Please complete the immunogenicity assessment and Central Lab Swab page. Thanks!' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 18:41:31
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:41:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	22 Sep 2020 12:30:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 15:03:39
User entered 'Yes (Y)' reason for change: Data Entry Error	System	31 Aug 2020 15:03:39
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	31 Aug 2020 15:03:39
User entered empty; reason for change Data Entry Error	System	25 Aug 2020 19:02:28
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:02:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 19:01:59
	(b) (4), (b) (6)	25 Aug 2020 18:55:52



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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:25:56

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:30:47
User entered '31 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 15:03:39
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:01:59
User entered '24 Aug 2020'	(b) (4), (b) (6)	25 Aug 2020 18:55:52

US3672278

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:25:56

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 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:30:47
User entered 'Clinic (Clinic)' reason for change:	(b) (4), (b) (6)	31 Aug 2020 15:03:39
Data Entry Error		
User entered empty; reason for change Data Entry	(b) (4), (b) (6)	25 Aug 2020 19:01:59
Error		
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	25 Aug 2020 18:55:52

**US3672278**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:25:56**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered 'VISIT1'	System	31 Aug 2020 15:03:39
User entered empty.	System	25 Aug 2020 19:02:28
User entered 'VISIT1'	System	25 Aug 2020 18:55:52

US3672278

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:25:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User closed query 'Per CDM: Please, complete Immunogenicity Assessment, Central Laboratory - Nasopharyngeal Swab as per CCGs. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 12:21:21
Query 'Per CDM: Please, complete Immunogenicity Assessment, Central Laboratory - Nasopharyngeal Swab as per CCGs. Thank you. ' answered with 'Completed.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 18:41:51
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:31:33
User opened query 'Per CDM: Please, complete Immunogenicity Assessment, Central Laboratory - Nasopharyngeal Swab as per CCGs. Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 06:25:16
User entered '31 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 15:04:45

US3672278

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:25:56

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	22 Sep 2020 12:31:33
User entered '188656'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 15:04:45

US3672278

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:25:56

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	22 Sep 2020 12:31:33
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 15:04:45

US3672278

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:25:56

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 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	22 Sep 2020 12:31:33
User closed query 'PER CDM: Please complete this section of the form.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 06:45:06
Query 'PER CDM: Please complete this section of the form.' answered with 'PATIENT DOES NOT HAVE CHRONIC LUNG DISEASE.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 18:53:28
User opened query 'PER CDM: Please complete this section of the form.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 19:34:01
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 15:04:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 15:04:04
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 15:04:04
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 19:02:12
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:02:12
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 18:56:08

US3672278

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:25:56

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 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 12:31:33
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 15:04:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 15:04:04
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 15:04:04
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 19:02:12
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:02:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 18:56:08



US3672278

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:25:56

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:31:33
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 15:04:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 15:04:04
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 15:04:04
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 19:02:12
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:02:12
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 18:56:08

US3672278

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:25:56

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:31:33
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 15:04:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 15:04:04
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 15:04:04
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 19:02:12
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:02:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 18:56:08

US3672278

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:25:56

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	22 Sep 2020 12:31:33
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 15:04:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 15:04:04
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Aug 2020 15:04:04
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Aug 2020 19:02:12
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	25 Aug 2020 19:02:12
User entered 'No (N)'	(b) (4), (b) (6)	25 Aug 2020 18:56:08

**US3672278**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:25:56**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 16:07:18
User entered 'No (N)'	(b) (4), (b) (6)	21 Oct 2020 17:38:19
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:40:16
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:42:33

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:25:56

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered '177.5' cm	(b) (4), (b) (6)	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:25:56

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered '96.8' kg	(b) (4), (b) (6)	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:25:56

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered '177.5' cm	(b) (4), (b) (6)	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:25:56

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered '96.8' kg	(b) (4), (b) (6)	31 Aug 2020 15:47:34



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 15:47:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered '31 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 15:47:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered '10:32'	(b) (4), (b) (6)	31 Aug 2020 15:47:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered '31 Aug 2020 10:32'	System	31 Aug 2020 15:47:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered '98.0' F	(b) (4), (b) (6)	31 Aug 2020 15:47:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered 'Oral (Oral)'	(b) (4), (b) (6)	31 Aug 2020 15:47:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 15:47:34



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered '60'	(b) (4), (b) (6)	31 Aug 2020 15:47:34

**US3672278**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered 'bpm'	System	31 Aug 2020 15:47:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered '16'	(b) (4), (b) (6)	31 Aug 2020 15:47:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered 'breaths/min'	System	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered '110'	(b) (4), (b) (6)	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered 'mmHg'	System	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	23 Oct 2020 05:29:59
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 15:26:02
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:37:48
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:21:38
User entered '58'	(b) (4), (b) (6)	31 Aug 2020 15:47:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered 'mmHg'	System	31 Aug 2020 15:47:34



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:25:56

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered '177.5' cm	(b) (4), (b) (6)	31 Aug 2020 15:47:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:25:56

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered '96.8' kg	(b) (4), (b) (6)	31 Aug 2020 15:47:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	31 Aug 2020 15:47:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User closed query 'Please complete post-dose information per source. Thanks' (Site from CRA).	(b) (4)	22 Oct 2020 15:56:26
Query 'Please complete post-dose information per source. Thanks' answered with 'Completed.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 18:44:24
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 18:44:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 18:44:12
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 18:44:12
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 18:44:12
User opened query 'Please complete post-dose information per source. Thanks' (Site from CRA).	(b) (4), (b) (6)	22 Sep 2020 12:39:21
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 15:47:34
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 15:47:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 18:44:12
User entered '31 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 15:47:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 18:44:12
User entered '12:04' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 15:47:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered '31 Aug 2020 12:04'	System	21 Oct 2020 18:44:12
User entered empty.	System	31 Aug 2020 15:47:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Oct 2020 18:44:29
User entered '97.7' F reason for change: Data Entry Error	System	21 Oct 2020 18:44:29
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	21 Oct 2020 18:44:29
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 18:44:12
User entered '97.7' (non-conformant).	(b) (4), (b) (6)	21 Oct 2020 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 15:47:34



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Un-verified.	(b) (4)	21 Oct 2020 18:44:12
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 15:47:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 15:47:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 18:44:12
User entered '68' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 15:47:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered 'bpm'	System	21 Oct 2020 18:44:12
User entered empty.	System	31 Aug 2020 15:47:34

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 18:44:12
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered 'breaths/min'	System	21 Oct 2020 18:44:12
User entered empty.	System	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 18:44:12
User entered '91' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered 'mmHg'	System	21 Oct 2020 18:44:12
User entered empty.	System	31 Aug 2020 15:47:34



US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 18:44:12
User entered '64' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 18:44:12
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:37:48
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered 'mmHg'	System	21 Oct 2020 18:44:12
User entered empty.	System	31 Aug 2020 15:47:34

US3672278

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:25:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:39:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 15:47:42

US3672278

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:25:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:39:32
User entered '31 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 15:47:42

US3672278

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:25:56

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:40:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 15:45:08

US3672278

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:25:56

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:40:20
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 15:45:08

US3672278

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:25:56

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 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:40:20
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 15:45:08

US3672278

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:25:56

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered 'MRNA-1273 OR PLACEBO'	System	31 Aug 2020 15:45:08



US3672278

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:25:56

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:40:20
User entered '31 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 15:45:08

**US3672278**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:25:56**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:40:20
User entered '11:25'	(b) (4), (b) (6)	31 Aug 2020 15:45:08

US3672278

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:25:56

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered '31 Aug 2020 11:25'	System	31 Aug 2020 15:45:08

US3672278

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:25:56

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:40:20
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	31 Aug 2020 15:45:08

US3672278

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:25:56

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:40:20
User entered 'ONCE'	System	31 Aug 2020 15:45:08

US3672278

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:25:56

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered 'INTRAMUSCULAR'	System	31 Aug 2020 15:45:08

US3672278

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:25:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:40:50

US3672278

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:25:56

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:40:50



**US3672278**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:25:56**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered '11:07'	(b) (4), (b) (6)	21 Oct 2020 18:40:50

**US3672278**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:25:56**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered '31 Aug 2020 11:07'	System	21 Oct 2020 18:40:50

**US3672278**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 09:25:56**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered '31 Aug 2020'	(b) (4), (b) (6)	21 Oct 2020 18:41:14

**US3672278**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	21 Oct 2020 18:41:14

US3672278

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:25:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:41:14

**US3672278**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:25:56**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered '10:49'	(b) (4), (b) (6)	21 Oct 2020 18:41:14

**US3672278**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered '31 Aug 2020 10:49'	System	21 Oct 2020 18:41:14

**US3672278**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:25:56**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	21 Oct 2020 18:41:14



US3672278

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:25:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:41:14

**US3672278**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:25:56**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered empty.	(b) (4), (b) (6)	21 Oct 2020 18:41:14

**US3672278**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:25:56**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered empty.	System	21 Oct 2020 18:41:14

**US3672278**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:25:56**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:40:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 18:30:11

**US3672278**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:25:56**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered 'I'	System	01 Sep 2020 18:30:11

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:25:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-08-31T11:57:22', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '5f463ee8-46fc-4c60-8b54-6299f5cbd047' User entered 'Yes (Y)'	System	31 Aug 2020 15:58:40
	System	31 Aug 2020 15:58:40

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:25:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-08-31T11:57:40', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '5f463ee8-46fc-4c60-8b54-6299f5cbd047' User entered '97.7'	System	31 Aug 2020 15:58:40
	System	31 Aug 2020 15:58:40



US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:25:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-08-31T11:57:49', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '5f463ee8-46fc-4c60-8b54-6299f5cbd047'	System	31 Aug 2020 15:58:40
User entered 'No (N)'	System	31 Aug 2020 15:58:40

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-08-31T11:58:03', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '5f463ee8-46fc-4c60-8b54-6299f5cbd047' User entered '31 Aug 2020 11:58'	System	31 Aug 2020 15:58:40
	System	31 Aug 2020 15:58:40

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:25:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '31 Aug 2020 11:45'	System	31 Aug 2020 15:45:08

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '31 Aug 2020 14:15'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:25:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T00:04:29', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'e543a863-4db2-4130-afe1-3b62f90b70b7' User entered 'Yes (Y)'	System	01 Sep 2020 04:05:01
	System	01 Sep 2020 04:05:01

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:25:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T00:04:42', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'e543a863-4db2-4130-afe1-3b62f90b70b7' User entered '96.7'	System	01 Sep 2020 04:05:01
	System	01 Sep 2020 04:05:01

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:25:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T00:04:49', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'e543a863-4db2-4130-afe1-3b62f90b70b7'	System	01 Sep 2020 04:05:01
User entered 'No (N)'	System	01 Sep 2020 04:05:01



**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T00:04:57', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'e543a863-4db2-4130-afe1-3b62f90b70b7' User entered '01 Sep 2020 00:04'	System	01 Sep 2020 04:05:01
	System	01 Sep 2020 04:05:01

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '31 Aug 2020 15:10'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:25:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 2'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:25:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T22:58:29', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '4e8d2419-92ec-4224-a5d9-2b1bba90bb1b' User entered 'Yes (Y)'	System	02 Sep 2020 02:59:02
	System	02 Sep 2020 02:59:02

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:25:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T22:58:43', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '4e8d2419-92ec-4224-a5d9-2b1bba90bb1b' User entered '96.1'	System	02 Sep 2020 02:59:02
	System	02 Sep 2020 02:59:02

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:25:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T22:58:49', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '4e8d2419-92ec-4224-a5d9-2b1bba90bb1b' User entered 'No (N)'	System	02 Sep 2020 02:59:02
	System	02 Sep 2020 02:59:02

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T22:58:58', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '4e8d2419-92ec-4224-a5d9-2b1bba90bb1b' User entered '01 Sep 2020 22:58'	System	02 Sep 2020 02:59:02
	System	02 Sep 2020 02:59:02



**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:25:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 3'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:25:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T00:02:47', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '79bcf885-7b57-47cd-870a-dc03346d5db4' User entered 'Yes (Y)'	System	03 Sep 2020 04:03:15
	System	03 Sep 2020 04:03:15

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:25:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T00:03:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '79bcf885-7b57-47cd-870a-dc03346d5db4' User entered '97.1'	System	03 Sep 2020 04:03:15
	System	03 Sep 2020 04:03:15

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:25:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T00:03:07', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '79bcf885-7b57-47cd-870a-dc03346d5db4'	System	03 Sep 2020 04:03:15
User entered 'No (N)'	System	03 Sep 2020 04:03:15

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T00:03:14', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '79bcf885-7b57-47cd-870a-dc03346d5db4' User entered '03 Sep 2020 00:03'	System	03 Sep 2020 04:03:15
	System	03 Sep 2020 04:03:15

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 15:45:08



US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:25:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 4'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:25:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T23:38:35', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd4b6b1d6-eb36-40a6-aed8-1a4483ddd93f' User entered 'Yes (Y)'	System	04 Sep 2020 03:39:03
	System	04 Sep 2020 03:39:03

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:25:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T23:38:44', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd4b6b1d6-eb36-40a6-aed8-1a4483ddd93f' User entered '96.6'	System	04 Sep 2020 03:39:03
	System	04 Sep 2020 03:39:03

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:25:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T23:38:51', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd4b6b1d6-eb36-40a6-aed8-1a4483ddd93f' User entered 'No (N)'	System	04 Sep 2020 03:39:03
	System	04 Sep 2020 03:39:03

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:25:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T23:38:59', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd4b6b1d6-eb36-40a6-aed8-1a4483ddd93f' User entered '03 Sep 2020 23:38'	System	04 Sep 2020 03:39:03
	System	04 Sep 2020 03:39:03

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 15:45:08

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 15:45:08



US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 5'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:25:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-04T22:55:48', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '7491bc0e-daed-4849-b568-9d4c0e1f901a' User entered 'Yes (Y)'	System	05 Sep 2020 02:56:20
	System	05 Sep 2020 02:56:20

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:25:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-04T22:56:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '7491bc0e-daed-4849-b568-9d4c0e1f901a' User entered '97.2'	System	05 Sep 2020 02:56:20
	System	05 Sep 2020 02:56:20

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:25:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-04T22:56:10', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '7491bc0e-daed-4849-b568-9d4c0e1f901a' User entered 'No (N)'	System	05 Sep 2020 02:56:20
	System	05 Sep 2020 02:56:20

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-04T22:56:17', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '7491bc0e-daed-4849-b568-9d4c0e1f901a' User entered '04 Sep 2020 22:56'	System	05 Sep 2020 02:56:20
	System	05 Sep 2020 02:56:20

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 15:45:08

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 6'	System	31 Aug 2020 15:45:08



US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:25:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-05T23:13:30', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd95d0d83-330a-440b-9d8a-7b708c56eedd' User entered 'Yes (Y)'	System	06 Sep 2020 03:14:00
	System	06 Sep 2020 03:14:00

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:25:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-05T23:13:41', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd95d0d83-330a-440b-9d8a-7b708c56eedd' User entered '96.9'	System	06 Sep 2020 03:14:00
	System	06 Sep 2020 03:14:00

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:25:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-05T23:13:48', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd95d0d83-330a-440b-9d8a-7b708c56eedd'	System	06 Sep 2020 03:14:00
User entered 'No (N)'	System	06 Sep 2020 03:14:00

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-05T23:13:55', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd95d0d83-330a-440b-9d8a-7b708c56eedd' User entered '05 Sep 2020 23:13'	System	06 Sep 2020 03:14:00
	System	06 Sep 2020 03:14:00

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:25:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 15:45:08

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 7'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:25:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-06T23:09:42', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '2a1a7cc8-ca55-4b5a-84b3-7f2fd43bdaf6' User entered 'Yes (Y)'	System	07 Sep 2020 03:10:11
	System	07 Sep 2020 03:10:11



US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:25:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-06T23:09:52', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '2a1a7cc8-ca55-4b5a-84b3-7f2fd43bdaf6' User entered '97.6'	System	07 Sep 2020 03:10:11
	System	07 Sep 2020 03:10:11

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:25:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-06T23:09:58', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '2a1a7cc8-ca55-4b5a-84b3-7f2fd43bdaf6'	System	07 Sep 2020 03:10:11
User entered 'No (N)'	System	07 Sep 2020 03:10:11

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-06T23:10:06', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '2a1a7cc8-ca55-4b5a-84b3-7f2fd43bdaf6' User entered '06 Sep 2020 23:10'	System	07 Sep 2020 03:10:11
	System	07 Sep 2020 03:10:11

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:25:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:25:56

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 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-08-31T11:58:40', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd155c3e9-ed0b-4d98-aaa6-b834d41efd6e' User entered 'Does not interfere with activity (2)'	System	31 Aug 2020 16:01:56
	System	31 Aug 2020 16:01:56

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:25:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-08-31T11:59:07', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd155c3e9-ed0b-4d98-aaa6-b834d41efd6e' User entered 'Yes (Y)'	System	31 Aug 2020 16:01:56
	System	31 Aug 2020 16:01:56



US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:25:56

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-08-31T12:00:13', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd155c3e9-ed0b-4d98-aaa6-b834d41efd6e' User entered '4'	System	31 Aug 2020 16:01:56
	System	31 Aug 2020 16:01:56

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:25:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-08-31T12:00:21', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd155c3e9-ed0b-4d98-aaa6-b834d41efd6e' User entered 'No (N)'	System	31 Aug 2020 16:01:56
	System	31 Aug 2020 16:01:56

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:25:56

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 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-08-31T12:00:33', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd155c3e9-ed0b-4d98-aaa6-b834d41efd6e' User entered 'None (1)'	System	31 Aug 2020 16:01:56
	System	31 Aug 2020 16:01:56

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-08-31T12:00:56', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd155c3e9-ed0b-4d98-aaa6-b834d41efd6e' User entered '31 Aug 2020 12:00'	System	31 Aug 2020 16:01:56
	System	31 Aug 2020 16:01:56

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '31 Aug 2020 11:45'	System	31 Aug 2020 15:45:08

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '31 Aug 2020 14:15'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:25:56

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 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T00:01:36', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '57f3402c-e476-4bc8-b2fc-c424dec80591' User entered 'None (1)'	System	01 Sep 2020 04:05:45
	System	01 Sep 2020 04:05:45



US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:25:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T00:01:42', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '57f3402c-e476-4bc8-b2fc-c424dec80591' User entered 'Yes (Y)'	System	01 Sep 2020 04:05:45
	System	01 Sep 2020 04:05:45

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:25:56

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T00:01:51', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '57f3402c-e476-4bc8-b2fc-c424dec80591' User entered '2'	System	01 Sep 2020 04:05:45
	System	01 Sep 2020 04:05:45

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:25:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T00:01:56', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '57f3402c-e476-4bc8-b2fc-c424dec80591' User entered 'No (N)'	System	01 Sep 2020 04:05:45
	System	01 Sep 2020 04:05:45

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:25:56

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 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T00:05:25', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '57f3402c-e476-4bc8-b2fc-c424dec80591' User entered 'None (1)'	System	01 Sep 2020 04:05:45
	System	01 Sep 2020 04:05:45

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:25:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T00:05:40', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '57f3402c-e476-4bc8-b2fc-c424dec80591' User entered '01 Sep 2020 00:05'	System	01 Sep 2020 04:05:45
	System	01 Sep 2020 04:05:45

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '31 Aug 2020 15:10'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:25:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 2'	System	31 Aug 2020 15:45:08



US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:25:56

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 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T22:59:15', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd6a07af6-b09d-46fc-ad61-aa47ad3e3397'	System	02 Sep 2020 02:59:56
User entered 'None (1)'	System	02 Sep 2020 02:59:56

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:25:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T22:59:25', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd6a07af6-b09d-46fc-ad61-aa47ad3e3397'	System	02 Sep 2020 02:59:56
User entered 'No (N)'	System	02 Sep 2020 02:59:56

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:25:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T22:59:32', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd6a07af6-b09d-46fc-ad61-aa47ad3e3397'	System	02 Sep 2020 02:59:56
User entered 'No (N)'	System	02 Sep 2020 02:59:56

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:25:56

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 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T22:59:42', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd6a07af6-b09d-46fc-ad61-aa47ad3e3397'	System	02 Sep 2020 02:59:56
User entered 'None (1)'	System	02 Sep 2020 02:59:56

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T22:59:54', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd6a07af6-b09d-46fc-ad61-aa47ad3e3397'	System	02 Sep 2020 02:59:56
User entered '01 Sep 2020 22:59'	System	02 Sep 2020 02:59:56

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 15:45:08

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 3'	System	31 Aug 2020 15:45:08



US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:25:56

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 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T00:03:23', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd260181a-86ee-46fb-969b-b0108e05b739' User entered 'None (1)'	System	03 Sep 2020 04:03:50
	System	03 Sep 2020 04:03:50

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:25:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T00:03:28', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd260181a-86ee-46fb-969b-b0108e05b739' User entered 'No (N)'	System	03 Sep 2020 04:03:50
	System	03 Sep 2020 04:03:50

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:25:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T00:03:33', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd260181a-86ee-46fb-969b-b0108e05b739' User entered 'No (N)'	System	03 Sep 2020 04:03:50
	System	03 Sep 2020 04:03:50

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:25:56

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 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T00:03:39', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd260181a-86ee-46fb-969b-b0108e05b739' User entered 'None (1)'	System	03 Sep 2020 04:03:50
	System	03 Sep 2020 04:03:50

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T00:03:49', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd260181a-86ee-46fb-969b-b0108e05b739' User entered '03 Sep 2020 00:03'	System	03 Sep 2020 04:03:50
	System	03 Sep 2020 04:03:50

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 15:45:08

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 4'	System	31 Aug 2020 15:45:08



US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:25:56

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 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T23:39:08', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'a9e15647-d581-49c1-bf56-fcbea2609b61' User entered 'None (1)'	System	04 Sep 2020 03:39:41
	System	04 Sep 2020 03:39:41

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:25:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T23:39:15', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'a9e15647-d581-49c1-bf56-fcbea2609b61' User entered 'No (N)'	System	04 Sep 2020 03:39:41
	System	04 Sep 2020 03:39:41

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:25:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T23:39:20', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'a9e15647-d581-49c1-bf56-fcbea2609b61' User entered 'No (N)'	System	04 Sep 2020 03:39:41
	System	04 Sep 2020 03:39:41

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:25:56

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 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T23:39:27', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'a9e15647-d581-49c1-bf56-fcbea2609b61' User entered 'None (1)'	System	04 Sep 2020 03:39:41
	System	04 Sep 2020 03:39:41

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:25:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T23:39:37', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'a9e15647-d581-49c1-bf56-fcbea2609b61' User entered '03 Sep 2020 23:39'	System	04 Sep 2020 03:39:41
	System	04 Sep 2020 03:39:41

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:25:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 15:45:08

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 5'	System	31 Aug 2020 15:45:08



US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:25:56

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 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-04T22:56:28', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '47ae921c-a9d6-4b63-8766-c69790682a31' User entered 'None (1)'	System	05 Sep 2020 02:56:53
	System	05 Sep 2020 02:56:53

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:25:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-04T22:56:34', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '47ae921c-a9d6-4b63-8766-c69790682a31' User entered 'No (N)'	System	05 Sep 2020 02:56:53
	System	05 Sep 2020 02:56:53

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:25:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-04T22:56:38', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '47ae921c-a9d6-4b63-8766-c69790682a31' User entered 'No (N)'	System	05 Sep 2020 02:56:53
	System	05 Sep 2020 02:56:53

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:25:56

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 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-04T22:56:43', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '47ae921c-a9d6-4b63-8766-c69790682a31' User entered 'None (1)'	System	05 Sep 2020 02:56:53
	System	05 Sep 2020 02:56:53

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:25:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-04T22:56:50', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '47ae921c-a9d6-4b63-8766-c69790682a31' User entered '04 Sep 2020 22:56'	System	05 Sep 2020 02:56:53
	System	05 Sep 2020 02:56:53

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 15:45:08

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 6'	System	31 Aug 2020 15:45:08



US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:25:56

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 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-05T23:14:03', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd2d3e504-e524-425b-b25c-df30b33fa5ff' User entered 'None (1)'	System	06 Sep 2020 03:14:31
	System	06 Sep 2020 03:14:31

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:25:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-05T23:14:09', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd2d3e504-e524-425b-b25c-df30b33fa5ff' User entered 'No (N)'	System	06 Sep 2020 03:14:31
	System	06 Sep 2020 03:14:31

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:25:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-05T23:14:14', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd2d3e504-e524-425b-b25c-df30b33fa5ff' User entered 'No (N)'	System	06 Sep 2020 03:14:31
	System	06 Sep 2020 03:14:31

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:25:56

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 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-05T23:14:20', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd2d3e504-e524-425b-b25c-df30b33fa5ff' User entered 'None (1)'	System	06 Sep 2020 03:14:31
	System	06 Sep 2020 03:14:31

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-05T23:14:28', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd2d3e504-e524-425b-b25c-df30b33fa5ff' User entered '05 Sep 2020 23:14'	System	06 Sep 2020 03:14:31
	System	06 Sep 2020 03:14:31

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 15:45:08

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 7'	System	31 Aug 2020 15:45:08



US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:25:56

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 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-06T23:10:14', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'b3590ff1-deb3-48f3-b558-da9ed67856fd' User entered 'None (1)'	System	07 Sep 2020 03:10:47
	System	07 Sep 2020 03:10:47

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:25:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-06T23:10:20', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'b3590ff1-deb3-48f3-b558-da9ed67856fd' User entered 'No (N)'	System	07 Sep 2020 03:10:47
	System	07 Sep 2020 03:10:47

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:25:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-06T23:10:25', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'b3590ff1-deb3-48f3-b558-da9ed67856fd' User entered 'No (N)'	System	07 Sep 2020 03:10:47
	System	07 Sep 2020 03:10:47

US3672278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:25:56

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 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-06T23:10:33', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'b3590ff1-deb3-48f3-b558-da9ed67856fd' User entered 'None (1)'	System	07 Sep 2020 03:10:47
	System	07 Sep 2020 03:10:47

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-06T23:10:44', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'b3590ff1-deb3-48f3-b558-da9ed67856fd' User entered '06 Sep 2020 23:10'	System	07 Sep 2020 03:10:47
	System	07 Sep 2020 03:10:47

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 15:45:08

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 15:45:08



US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:25:56

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-08-31T12:01:16', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '9473c0fa-778d-42e1-9ea5-ce4d87527767' User entered 'None (0)'	System	31 Aug 2020 16:03:16
	System	31 Aug 2020 16:03:16

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:25:56

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-08-31T12:01:22', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '9473c0fa-778d-42e1-9ea5-ce4d87527767' User entered 'None (0)'	System	31 Aug 2020 16:03:16
	System	31 Aug 2020 16:03:16

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:25:56

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-08-31T12:01:27', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '9473c0fa-778d-42e1-9ea5-ce4d87527767' User entered 'None (0)'	System	31 Aug 2020 16:03:16
	System	31 Aug 2020 16:03:16

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:25:56

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-08-31T12:01:34', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '9473c0fa-778d-42e1-9ea5-ce4d87527767' User entered 'None (0)'	System	31 Aug 2020 16:03:16
	System	31 Aug 2020 16:03:16

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:25:56

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-08-31T12:01:41', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '9473c0fa-778d-42e1-9ea5-ce4d87527767' User entered 'None (0)'	System	31 Aug 2020 16:03:16
	System	31 Aug 2020 16:03:16

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:25:56**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-08-31T12:01:46', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '9473c0fa-778d-42e1-9ea5-ce4d87527767' User entered 'None (0)'	System	31 Aug 2020 16:03:16
	System	31 Aug 2020 16:03:16

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:25:56

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 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-08-31T12:01:53', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '9473c0fa-778d-42e1-9ea5-ce4d87527767' User entered 'No (N)'	System	31 Aug 2020 16:03:16
	System	31 Aug 2020 16:03:16

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-08-31T12:02:03', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '9473c0fa-778d-42e1-9ea5-ce4d87527767' User entered '31 Aug 2020 12:02'	System	31 Aug 2020 16:03:16
	System	31 Aug 2020 16:03:16



US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:25:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '31 Aug 2020 11:45'	System	31 Aug 2020 15:45:08

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '31 Aug 2020 14:15'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:25:56

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T00:02:47', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'c701adb8-3e56-4711-8a9e-981584f046eb' User entered 'None (0)'	System	01 Sep 2020 04:04:06
	System	01 Sep 2020 04:04:06

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:25:56

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T00:03:01', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'c701adb8-3e56-4711-8a9e-981584f046eb' User entered 'None (0)'	System	01 Sep 2020 04:04:06
	System	01 Sep 2020 04:04:06

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:25:56**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T00:03:05', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'c701adb8-3e56-4711-8a9e-981584f046eb' User entered 'None (0)'	System	01 Sep 2020 04:04:06
	System	01 Sep 2020 04:04:06

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:25:56

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T00:03:10', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'c701adb8-3e56-4711-8a9e-981584f046eb' User entered 'None (0)'	System	01 Sep 2020 04:04:06
	System	01 Sep 2020 04:04:06

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:25:56

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T00:03:18', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'c701adb8-3e56-4711-8a9e-981584f046eb' User entered 'None (0)'	System	01 Sep 2020 04:04:06
	System	01 Sep 2020 04:04:06



**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:25:56**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T00:03:29', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'c701adb8-3e56-4711-8a9e-981584f046eb' User entered 'None (0)'	System	01 Sep 2020 04:04:06
	System	01 Sep 2020 04:04:06

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:25:56

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 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T00:03:36', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'c701adb8-3e56-4711-8a9e-981584f046eb' User entered 'No (N)'	System	01 Sep 2020 04:04:06
	System	01 Sep 2020 04:04:06

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T00:04:03', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'c701adb8-3e56-4711-8a9e-981584f046eb' User entered '01 Sep 2020 00:04'	System	01 Sep 2020 04:04:06
	System	01 Sep 2020 04:04:06

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '31 Aug 2020 15:10'	System	31 Aug 2020 15:45:08

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 2'	System	31 Aug 2020 15:45:08

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:25:56**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T23:00:08', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'cbaf3108-f0a7-4042-b358-c69941cef53b' User entered 'None (0)'	System	02 Sep 2020 03:01:11
	System	02 Sep 2020 03:01:11

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:25:56

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T23:00:12', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'cbaf3108-f0a7-4042-b358-c69941cef53b' User entered 'None (0)'	System	02 Sep 2020 03:01:11
	System	02 Sep 2020 03:01:11



US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:25:56

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T23:00:17', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'cbaf3108-f0a7-4042-b358-c69941cef53b' User entered 'None (0)'	System	02 Sep 2020 03:01:11
	System	02 Sep 2020 03:01:11

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:25:56

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T23:00:21', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'cbaf3108-f0a7-4042-b358-c69941cef53b' User entered 'None (0)'	System	02 Sep 2020 03:01:11
	System	02 Sep 2020 03:01:11

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:25:56**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T23:00:34', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'cbaf3108-f0a7-4042-b358-c69941cef53b' User entered 'None (0)'	System	02 Sep 2020 03:01:11
	System	02 Sep 2020 03:01:11

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:25:56

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T23:00:41', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'cbaf3108-f0a7-4042-b358-c69941cef53b' User entered 'None (0)'	System	02 Sep 2020 03:01:11
	System	02 Sep 2020 03:01:11

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:25:56

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 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T23:00:50', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'cbaf3108-f0a7-4042-b358-c69941cef53b' User entered 'No (N)'	System	02 Sep 2020 03:01:11
	System	02 Sep 2020 03:01:11

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-01T23:01:06', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'cbaf3108-f0a7-4042-b358-c69941cef53b' User entered '01 Sep 2020 23:01'	System	02 Sep 2020 03:01:11
	System	02 Sep 2020 03:01:11

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 15:45:08

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 15:45:08



**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 3'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:25:56

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T00:03:55', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'c340e86c-f272-4340-9c66-49360aada8b2' User entered 'None (0)'	System	03 Sep 2020 04:04:54
	System	03 Sep 2020 04:04:54

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:25:56**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T00:04:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'c340e86c-f272-4340-9c66-49360aada8b2' User entered 'None (0)'	System	03 Sep 2020 04:04:54
	System	03 Sep 2020 04:04:54

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:25:56

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T00:04:03', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'c340e86c-f272-4340-9c66-49360aada8b2' User entered 'None (0)'	System	03 Sep 2020 04:04:54
	System	03 Sep 2020 04:04:54

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:25:56

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T00:04:09', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'c340e86c-f272-4340-9c66-49360aada8b2' User entered 'None (0)'	System	03 Sep 2020 04:04:54
	System	03 Sep 2020 04:04:54

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:25:56

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T00:04:14', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'c340e86c-f272-4340-9c66-49360aada8b2' User entered 'None (0)'	System	03 Sep 2020 04:04:54
	System	03 Sep 2020 04:04:54

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:25:56

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T00:04:18', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'c340e86c-f272-4340-9c66-49360aada8b2' User entered 'None (0)'	System	03 Sep 2020 04:04:54
	System	03 Sep 2020 04:04:54

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:25:56

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 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T00:04:36', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'c340e86c-f272-4340-9c66-49360aada8b2' User entered 'No (N)'	System	03 Sep 2020 04:04:54
	System	03 Sep 2020 04:04:54



US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:25:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T00:04:49', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'c340e86c-f272-4340-9c66-49360aada8b2' User entered '03 Sep 2020 00:04'	System	03 Sep 2020 04:04:54
	System	03 Sep 2020 04:04:54

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 15:45:08

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 4'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:25:56

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T23:39:46', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '7a8c59c6-c9ce-46bd-9520-045971ddda35' User entered 'None (0)'	System	04 Sep 2020 03:40:33
	System	04 Sep 2020 03:40:33

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:25:56

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T23:39:51', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '7a8c59c6-c9ce-46bd-9520-045971ddda35' User entered 'None (0)'	System	04 Sep 2020 03:40:33
	System	04 Sep 2020 03:40:33

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:25:56

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T23:39:55', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '7a8c59c6-c9ce-46bd-9520-045971ddda35' User entered 'None (0)'	System	04 Sep 2020 03:40:33
	System	04 Sep 2020 03:40:33

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:25:56

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T23:40:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '7a8c59c6-c9ce-46bd-9520-045971ddda35' User entered 'None (0)'	System	04 Sep 2020 03:40:33
	System	04 Sep 2020 03:40:33



US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:25:56

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T23:40:05', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '7a8c59c6-c9ce-46bd-9520-045971ddda35' User entered 'None (0)'	System	04 Sep 2020 03:40:33
	System	04 Sep 2020 03:40:33

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:25:56

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T23:40:08', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '7a8c59c6-c9ce-46bd-9520-045971ddda35' User entered 'None (0)'	System	04 Sep 2020 03:40:33
	System	04 Sep 2020 03:40:33

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:25:56

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 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T23:40:21', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '7a8c59c6-c9ce-46bd-9520-045971ddda35' User entered 'No (N)'	System	04 Sep 2020 03:40:33
	System	04 Sep 2020 03:40:33

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:25:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-03T23:40:32', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '7a8c59c6-c9ce-46bd-9520-045971ddda35' User entered '03 Sep 2020 23:40'	System	04 Sep 2020 03:40:33
	System	04 Sep 2020 03:40:33

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 15:45:08

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 15:45:08

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 5'	System	31 Aug 2020 15:45:08

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:25:56**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-04T22:56:58', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'db708bcf-2d3e-44d8-a7f2-963ac7ac9043' User entered 'None (0)'	System	05 Sep 2020 02:57:52
	System	05 Sep 2020 02:57:52



US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:25:56

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-04T22:57:02', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'db708bcf-2d3e-44d8-a7f2-963ac7ac9043' User entered 'None (0)'	System	05 Sep 2020 02:57:52
	System	05 Sep 2020 02:57:52

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:25:56

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-04T22:57:06', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'db708bcf-2d3e-44d8-a7f2-963ac7ac9043' User entered 'None (0)'	System	05 Sep 2020 02:57:52
	System	05 Sep 2020 02:57:52

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:25:56

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-04T22:57:10', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'db708bcf-2d3e-44d8-a7f2-963ac7ac9043' User entered 'None (0)'	System	05 Sep 2020 02:57:52
	System	05 Sep 2020 02:57:52

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:25:56**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-04T22:57:15', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'db708bcf-2d3e-44d8-a7f2-963ac7ac9043' User entered 'None (0)'	System	05 Sep 2020 02:57:52
	System	05 Sep 2020 02:57:52

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:25:56**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-04T22:57:21', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'db708bcf-2d3e-44d8-a7f2-963ac7ac9043' User entered 'None (0)'	System	05 Sep 2020 02:57:52
	System	05 Sep 2020 02:57:52

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:25:56

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 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-04T22:57:36', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'db708bcf-2d3e-44d8-a7f2-963ac7ac9043'	System	05 Sep 2020 02:57:52
User entered 'No (N)'	System	05 Sep 2020 02:57:52

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-04T22:57:49', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'db708bcf-2d3e-44d8-a7f2-963ac7ac9043' User entered '04 Sep 2020 22:57'	System	05 Sep 2020 02:57:52
	System	05 Sep 2020 02:57:52

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 15:45:08



**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 6'	System	31 Aug 2020 15:45:08

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:25:56

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-05T23:14:36', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '8026e0ff-982c-4418-a441-45a538a2afcd' User entered 'None (0)'	System	06 Sep 2020 03:15:16
	System	06 Sep 2020 03:15:16

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:25:56

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-05T23:14:40', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '8026e0ff-982c-4418-a441-45a538a2afcd' User entered 'None (0)'	System	06 Sep 2020 03:15:16
	System	06 Sep 2020 03:15:16

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:25:56

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-05T23:14:44', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '8026e0ff-982c-4418-a441-45a538a2afcd' User entered 'None (0)'	System	06 Sep 2020 03:15:16
	System	06 Sep 2020 03:15:16

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:25:56

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-05T23:14:48', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '8026e0ff-982c-4418-a441-45a538a2afcd' User entered 'None (0)'	System	06 Sep 2020 03:15:16
	System	06 Sep 2020 03:15:16

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:25:56

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-05T23:14:52', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '8026e0ff-982c-4418-a441-45a538a2afcd' User entered 'None (0)'	System	06 Sep 2020 03:15:16
	System	06 Sep 2020 03:15:16

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:25:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-05T23:14:56', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '8026e0ff-982c-4418-a441-45a538a2afcd' User entered 'None (0)'	System	06 Sep 2020 03:15:16
	System	06 Sep 2020 03:15:16



US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:25:56

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 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-05T23:15:02', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '8026e0ff-982c-4418-a441-45a538a2afcd' User entered 'No (N)'	System	06 Sep 2020 03:15:16
	System	06 Sep 2020 03:15:16

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-05T23:15:15', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '8026e0ff-982c-4418-a441-45a538a2afcd' User entered '05 Sep 2020 23:15'	System	06 Sep 2020 03:15:16
	System	06 Sep 2020 03:15:16

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 15:45:08

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 15:45:08

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 7'	System	31 Aug 2020 15:45:08

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:25:56**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-06T23:10:52', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '9134aa1e-9351-4652-842d-28f2df59b75a' User entered 'None (0)'	System	07 Sep 2020 03:11:32
	System	07 Sep 2020 03:11:32

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:25:56

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-06T23:10:55', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '9134aa1e-9351-4652-842d-28f2df59b75a' User entered 'None (0)'	System	07 Sep 2020 03:11:32
	System	07 Sep 2020 03:11:32

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:25:56

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-06T23:11:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '9134aa1e-9351-4652-842d-28f2df59b75a' User entered 'None (0)'	System	07 Sep 2020 03:11:32
	System	07 Sep 2020 03:11:32



US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:25:56

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-06T23:11:04', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '9134aa1e-9351-4652-842d-28f2df59b75a' User entered 'None (0)'	System	07 Sep 2020 03:11:32
	System	07 Sep 2020 03:11:32

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:25:56**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-06T23:11:08', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '9134aa1e-9351-4652-842d-28f2df59b75a' User entered 'None (0)'	System	07 Sep 2020 03:11:32
	System	07 Sep 2020 03:11:32

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:25:56**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-06T23:11:12', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '9134aa1e-9351-4652-842d-28f2df59b75a' User entered 'None (0)'	System	07 Sep 2020 03:11:32
	System	07 Sep 2020 03:11:32

US3672278

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:25:56

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 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-06T23:11:20', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '9134aa1e-9351-4652-842d-28f2df59b75a' User entered 'No (N)'	System	07 Sep 2020 03:11:32
	System	07 Sep 2020 03:11:32

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-09-06T23:11:29', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '9134aa1e-9351-4652-842d-28f2df59b75a' User entered '06 Sep 2020 23:11'	System	07 Sep 2020 03:11:32
	System	07 Sep 2020 03:11:32

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 15:45:08

**US3672278**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:25:56**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 15:45:08

**US3672278**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:25:56**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:44:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 18:56:29



US3672278

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:56

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	22 Sep 2020 12:44:21
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	14 Sep 2020 04:52:46
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'added pd due to subject being oow ' (Site from System).	(b) (4), (b) (6)	11 Sep 2020 18:57:06
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	11 Sep 2020 18:56:29
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 18:56:29

US3672278

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:44:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Sep 2020 18:56:29

US3672278

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:56

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:44:21
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 18:56:29

US3672278

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:44:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 18:57:25

**US3672278**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:25:56**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered 'I'	System	11 Sep 2020 18:57:25

**US3672278**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:25:56**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 19:29:25

**US3672278**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered '15 Sep 2020'	(b) (4), (b) (6)	15 Sep 2020 19:29:25

US3672278

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	15 Sep 2020 19:29:25



US3672278

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:56

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 19:29:25

US3672278

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:29:29

**US3672278**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:25:56**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered 'I'	System	15 Sep 2020 19:29:29

**US3672278**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:25:56**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:12:54

**US3672278**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:12:54

US3672278

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:12:54

US3672278

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:56

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:12:54

US3672278

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 20:13:01



**US3672278**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:25:56**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered 'I'	System	21 Sep 2020 20:13:01

US3672278

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:25:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 20:19:01

US3672278

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:25:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 20:19:01

US3672278

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:25:56

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 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 20:19:01

**US3672278**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:25:56**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered 'VISIT2'	System	28 Sep 2020 20:19:01

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	28 Sep 2020 20:19:39

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 20:19:39

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 20:19:39



US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered '10:16'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 20:19:39

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered '28 Sep 2020 10:16'	System	28 Sep 2020 20:19:39

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered '97.9' F	(b) (4), (b) (6)	28 Sep 2020 20:19:39

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 20:19:39

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 20:19:39

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered '77'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 20:19:39

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered 'bpm'	System	28 Sep 2020 20:19:39

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered '16'	(b) (4), (b) (6)	28 Sep 2020 20:19:39



US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered 'breaths/min'	System	28 Sep 2020 20:19:39

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered '105'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 20:19:39

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered 'mmHg'	System	28 Sep 2020 20:19:39

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered '68'	(b) (4), (b) (6)	28 Sep 2020 20:19:39

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered 'mmHg'	System	28 Sep 2020 20:19:39

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	28 Sep 2020 20:19:44

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 20:19:44

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:19:44



US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 20:19:44

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered empty.	System	28 Sep 2020 20:19:44

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 20:19:44

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 20:19:44

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 20:19:44

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 20:19:44

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered empty.	System	28 Sep 2020 20:19:44

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 20:19:44



US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered empty.	System	28 Sep 2020 20:19:44

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 20:19:44

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered empty.	System	28 Sep 2020 20:19:44

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 20:19:44

US3672278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered empty.	System	28 Sep 2020 20:19:44

US3672278

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:25:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 20:19:53

US3672278

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:25:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 20:19:53

US3672278

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:56

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 20:20:21



US3672278

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:56

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User closed query 'Per CDM: Please complete 'Dosing Discontinuation' page. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 04:58:58
Query 'Per CDM: Please complete 'Dosing Discontinuation' page. Thank you.' answered with 'CRF COMPLETED' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 23:14:37
User opened query 'Per CDM: Please complete 'Dosing Discontinuation' page. Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 05:32:04
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	(b) (4), (b) (6)	28 Sep 2020 20:20:21

US3672278

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:56

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 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:20:21

US3672278

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:56

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered empty.	System	28 Sep 2020 20:20:21

US3672278

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:56

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:20:21

US3672278

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:56

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 20:20:21

US3672278

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:56

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered empty.	System	28 Sep 2020 20:20:21

US3672278

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:56

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 20:20:21

US3672278

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:56

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered empty.	System	28 Sep 2020 20:20:21



US3672278

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:56

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered empty.	System	28 Sep 2020 20:20:21

US3672278

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:25:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 20:20:35

US3672278

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:25:56

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 20:20:35

US3672278

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:25:56

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered '10:43'	(b) (4), (b) (6)	28 Sep 2020 20:20:35

**US3672278**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:25:56**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered '28 Sep 2020 10:43'	System	28 Sep 2020 20:20:35

US3672278

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:25:56

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 20:20:51

**US3672278**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	28 Sep 2020 20:20:51

US3672278

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:25:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 20:20:51



**US3672278**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:25:56**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered '10:30'	(b) (4), (b) (6)	28 Sep 2020 20:20:51

**US3672278**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered '28 Sep 2020 10:30'	System	28 Sep 2020 20:20:51

**US3672278**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:25:56**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	28 Sep 2020 20:20:51

US3672278

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:25:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 20:20:51

**US3672278**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:25:56**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:20:51

**US3672278**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:25:56**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered empty.	System	28 Sep 2020 20:20:51

US3672278

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 20:20:57

**US3672278**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:25:56**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered '1'	System	28 Sep 2020 20:20:57



**US3672278**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:25:56**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 23:25:21

US3672278

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered '6 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:25:21

US3672278

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:25:21

US3672278

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:56

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:25:21

US3672278

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:25:25

**US3672278**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:25:56**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered 'I'	System	12 Oct 2020 23:25:25

**US3672278**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:25:56**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Oct 2020 23:25:35

**US3672278**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered '12 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:25:35



US3672278

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:25:35

US3672278

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:56

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered empty.	(b) (4), (b) (6)	12 Oct 2020 23:25:35

US3672278

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 23:25:38

**US3672278**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:25:56**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered 'I'	System	12 Oct 2020 23:25:38

**US3672278**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:25:56**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 20:30:26

**US3672278**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 20:30:26

US3672278

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 20:30:26

US3672278

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:56

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 20:30:26



US3672278

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 20:30:29

**US3672278**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:25:56**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered 'I'	System	19 Oct 2020 20:30:29

**US3672278**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:25:56**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 15:59:09

**US3672278**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered '23 Oct 2020'	(b) (4), (b) (6)	23 Oct 2020 15:59:09

US3672278

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:25:56

[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 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:59:09

**US3672278**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:25:56**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered 'VISIT3'	System	23 Oct 2020 15:59:09

US3672278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:59:52

US3672278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered '23 Oct 2020'	(b) (4), (b) (6)	23 Oct 2020 15:59:52



US3672278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered '10:07'	(b) (4), (b) (6)	23 Oct 2020 15:59:52

**US3672278**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:25:56**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered '23 Oct 2020 10:07'	System	23 Oct 2020 15:59:52

US3672278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered '97.9' F	(b) (4), (b) (6)	23 Oct 2020 15:59:52

US3672278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:59:52

US3672278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 15:59:52

US3672278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered '79'	(b) (4), (b) (6)	23 Oct 2020 15:59:52

**US3672278**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:25:56**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered 'bpm'	System	23 Oct 2020 15:59:52

US3672278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered '17'	(b) (4), (b) (6)	23 Oct 2020 15:59:52



US3672278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered 'breaths/min'	System	23 Oct 2020 15:59:52

US3672278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered '97'	(b) (4), (b) (6)	23 Oct 2020 15:59:52

**US3672278**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:25:56**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered 'mmHg'	System	23 Oct 2020 15:59:52

US3672278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:07:21
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4), (b) (6)	23 Oct 2020 16:00:06
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		23 Oct 2020 15:59:52
User entered '54'	(b) (4), (b) (6)	23 Oct 2020 15:59:52

US3672278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered 'mmHg'	System	23 Oct 2020 15:59:52

**US3672278**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:25:56**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09

US3672278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:56

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09

US3672278

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:25:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:00:40



US3672278

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:25:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 16:00:40

US3672278

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:25:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:01:06

US3672278

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:25:56

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered '23 Oct 2020'	(b) (4), (b) (6)	23 Oct 2020 16:01:06

**US3672278**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:25:56**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered '10:15'	(b) (4), (b) (6)	23 Oct 2020 16:01:06

**US3672278**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:25:56**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered '23 Oct 2020 10:15'	System	23 Oct 2020 16:01:06

**US3672278**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:25:56**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	15 Feb 2021 20:08:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 16:01:13

**US3672278**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:25:56**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered 'I'	System	23 Oct 2020 16:01:13

US3672278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 64'	System	31 Aug 2020 15:45:08



US3672278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

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 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-10-31T19:03:22', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'a429dd47-49cf-4bad-b6bd-40c908666a78'	System	31 Oct 2020 23:04:05
User entered 'No (N)'	System	31 Oct 2020 23:04:05

US3672278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

Have you been exposed to someone with 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 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-10-31T19:03:33', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'a429dd47-49cf-4bad-b6bd-40c908666a78'	System	31 Oct 2020 23:04:05
User entered 'No (N)'	System	31 Oct 2020 23:04:05

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-10-31T19:04:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'a429dd47-49cf-4bad-b6bd-40c908666a78' User entered '31 Oct 2020 19:04:00'	System	31 Oct 2020 23:04:05
	System	31 Oct 2020 23:04:05

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
Data entry locked.	System	31 Aug 2020 15:45:08
User entered '31 Oct 2020 00:01'	System	31 Aug 2020 15:45:08

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
Data entry locked.	System	31 Aug 2020 15:45:08
User entered '04 Nov 2020 23:59'	System	31 Aug 2020 15:45:08

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 71'	System	31 Aug 2020 15:45:08

US3672278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

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 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-11-07T18:09:12', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'fbfb68c4-10b3-4f77-9809-940c5ba96723' User entered 'No (N)'	System	07 Nov 2020 23:09:57
	System	07 Nov 2020 23:09:57

US3672278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

Have you been exposed to someone with 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 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-11-07T18:09:20', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'fbfb68c4-10b3-4f77-9809-940c5ba96723' User entered 'No (N)'	System	07 Nov 2020 23:09:57
	System	07 Nov 2020 23:09:57



**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-11-07T18:09:54', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'fbfb68c4-10b3-4f77-9809-940c5ba96723' User entered '07 Nov 2020 18:09:54'	System	07 Nov 2020 23:09:57
	System	07 Nov 2020 23:09:57

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
Data entry locked.	System	31 Aug 2020 15:45:08
User entered '07 Nov 2020 00:01'	System	31 Aug 2020 15:45:08

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
Data entry locked.	System	31 Aug 2020 15:45:08
User entered '11 Nov 2020 23:59'	System	31 Aug 2020 15:45:08

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
Data entry locked.	System	31 Aug 2020 15:45:08
User entered 'Day 78'	System	31 Aug 2020 15:45:08

US3672278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

[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 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-11-14T23:29:10', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '53b57dd9-24f5-41d4-b9f1-13609f33e8c2' User entered 'No (N)'	System	15 Nov 2020 04:30:02
	System	15 Nov 2020 04:30:02

US3672278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:25:56

Have you been exposed to someone with 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 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-11-14T23:29:25', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '53b57dd9-24f5-41d4-b9f1-13609f33e8c2'	System	15 Nov 2020 04:30:02
User entered 'Yes (Y)'	System	15 Nov 2020 04:30:02

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-11-14T23:29:38', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '53b57dd9-24f5-41d4-b9f1-13609f33e8c2'	System	15 Nov 2020 04:30:02
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	15 Nov 2020 04:30:02

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-11-14T23:29:50', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '53b57dd9-24f5-41d4-b9f1-13609f33e8c2' User entered '14 Nov 2020 23:29:50'	System	15 Nov 2020 04:30:02
	System	15 Nov 2020 04:30:02



**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
Data entry locked.	System	31 Aug 2020 15:45:08
User entered '14 Nov 2020 00:01'	System	31 Aug 2020 15:45:08

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 06:40:32
Data entry locked.	System	31 Aug 2020 15:45:08
User entered '18 Nov 2020 23:59'	System	31 Aug 2020 15:45:08

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '18 Nov 2020 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '22 Nov 2020 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '25 Nov 2020 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '29 Nov 2020 23:59'	System	20 Nov 2020 01:53:12



**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-12-04T22:16:07', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'e23d8d63-8951-40b9-b614-55e9b627f6e4'	System	05 Dec 2020 03:16:33
User entered 'No (N)'	System	05 Dec 2020 03:16:33

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Have you been exposed to someone with 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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-12-04T22:16:17', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'e23d8d63-8951-40b9-b614-55e9b627f6e4'	System	05 Dec 2020 03:16:33
User entered 'No (N)'	System	05 Dec 2020 03:16:33

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-12-04T22:16:26', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'e23d8d63-8951-40b9-b614-55e9b627f6e4'	System	05 Dec 2020 03:16:33
User entered '04 Dec 2020 22:16:26'	System	05 Dec 2020 03:16:33

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-12-12T00:37:29', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '154d45af-47ca-4108-b5a0-ea290937abe2' User entered 'No (N)'	System	12 Dec 2020 05:44:46
	System	12 Dec 2020 05:44:46



**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Have you been exposed to someone with 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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-12-12T00:37:36', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '154d45af-47ca-4108-b5a0-ea290937abe2'	System	12 Dec 2020 05:44:46
User entered 'No (N)'	System	12 Dec 2020 05:44:46

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-12-12T00:37:47', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '154d45af-47ca-4108-b5a0-ea290937abe2' User entered '12 Dec 2020 00:37:47'	System	12 Dec 2020 05:44:46
	System	12 Dec 2020 05:44:46

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-12-16T22:32:48', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'cf2a7394-de93-42a8-841c-fe3341c2d208'	System	17 Dec 2020 03:33:04
User entered 'No (N)'	System	17 Dec 2020 03:33:04

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

Have you been exposed to someone with 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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-12-16T22:32:53', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'cf2a7394-de93-42a8-841c-fe3341c2d208'	System	17 Dec 2020 03:33:04
User entered 'No (N)'	System	17 Dec 2020 03:33:04

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-12-16T22:33:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'cf2a7394-de93-42a8-841c-fe3341c2d208' User entered '16 Dec 2020 22:33:00'	System	17 Dec 2020 03:33:04
	System	17 Dec 2020 03:33:04



**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-12-23T00:02:23', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'ce8eaa2c-940f-4659-af16-6dbf91956282'	System	23 Dec 2020 05:03:05
User entered 'No (N)'	System	23 Dec 2020 05:03:05

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

Have you been exposed to someone with 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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-12-23T00:02:32', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'ce8eaa2c-940f-4659-af16-6dbf91956282'	System	23 Dec 2020 05:03:05
User entered 'No (N)'	System	23 Dec 2020 05:03:05

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-12-23T00:02:48', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'ce8eaa2c-940f-4659-af16-6dbf91956282' User entered '23 Dec 2020 00:02:48'	System	23 Dec 2020 05:03:05
	System	23 Dec 2020 05:03:05

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 01:53:12



**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-12-30T21:37:39', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '3b54aaee-04d6-476a-9c3c-6d9ade70df86'	System	31 Dec 2020 02:38:01
User entered 'No (N)'	System	31 Dec 2020 02:38:01

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Have you been exposed to someone with 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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-12-30T21:37:51', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '3b54aaee-04d6-476a-9c3c-6d9ade70df86' User entered 'No (N)'	System	31 Dec 2020 02:38:01
	System	31 Dec 2020 02:38:01

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2020-12-30T21:37:59', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '3b54aaee-04d6-476a-9c3c-6d9ade70df86' User entered '30 Dec 2020 21:37:59'	System	31 Dec 2020 02:38:01
	System	31 Dec 2020 02:38:01

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-01-07T22:19:19', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '1c0d5024-944c-4bee-91ea-7facede21271' User entered 'No (N)'	System	08 Jan 2021 03:19:37
	System	08 Jan 2021 03:19:37



**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

Have you been exposed to someone with 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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-01-07T22:19:25', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '1c0d5024-944c-4bee-91ea-7facede21271' User entered 'No (N)'	System	08 Jan 2021 03:19:37

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-01-07T22:19:30', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '1c0d5024-944c-4bee-91ea-7facede21271' User entered '07 Jan 2021 22:19:30'	System	08 Jan 2021 03:19:37
	System	08 Jan 2021 03:19:37

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-01-13T17:49:18', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '9b87ecdc-ab07-459d-aba7-8f22f1b46684'	System	13 Jan 2021 22:49:35
User entered 'No (N)'	System	13 Jan 2021 22:49:35

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

Have you been exposed to someone with 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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-01-13T17:49:24', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '9b87ecdc-ab07-459d-aba7-8f22f1b46684'	System	13 Jan 2021 22:49:35
User entered 'No (N)'	System	13 Jan 2021 22:49:35

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-01-13T17:49:31', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '9b87ecdc-ab07-459d-aba7-8f22f1b46684' User entered '13 Jan 2021 17:49:31'	System	13 Jan 2021 22:49:35
	System	13 Jan 2021 22:49:35



**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-01-20T15:29:15', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '3aa88662-95dd-40b7-8eab-1bee1a098e33' User entered 'No (N)'	System	20 Jan 2021 20:29:33
	System	20 Jan 2021 20:29:33

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

Have you been exposed to someone with 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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-01-20T15:29:23', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '3aa88662-95dd-40b7-8eab-1bee1a098e33' User entered 'No (N)'	System	20 Jan 2021 20:29:33
	System	20 Jan 2021 20:29:33

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-01-20T15:29:29', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '3aa88662-95dd-40b7-8eab-1bee1a098e33' User entered '20 Jan 2021 15:29:29'	System	20 Jan 2021 20:29:33
	System	20 Jan 2021 20:29:33

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 01:53:12



**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-01-28T13:53:52', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '94cf3069-10af-420d-89fc-e40076dfd227'	System	28 Jan 2021 18:54:09
User entered 'No (N)'	System	28 Jan 2021 18:54:09

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

Have you been exposed to someone with 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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-01-28T13:53:58', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '94cf3069-10af-420d-89fc-e40076dfd227'	System	28 Jan 2021 18:54:09
User entered 'No (N)'	System	28 Jan 2021 18:54:09

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-01-28T13:54:04', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '94cf3069-10af-420d-89fc-e40076dfd227' User entered '28 Jan 2021 13:54:04'	System	28 Jan 2021 18:54:09

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-02-07T22:50:14', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'ec479632-2490-4b98-948b-28599a0b499e' User entered 'No (N)'	System	08 Feb 2021 03:51:41



**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

Have you been exposed to someone with 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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-02-07T22:50:20', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'ec479632-2490-4b98-948b-28599a0b499e' User entered 'No (N)'	System	08 Feb 2021 03:51:41

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-02-07T22:50:24', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'ec479632-2490-4b98-948b-28599a0b499e' User entered '07 Feb 2021 22:50:24'	System	08 Feb 2021 03:51:41
	System	08 Feb 2021 03:51:41

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 01:53:12



**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-02-17T14:33:14', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '1545c1a9-fbbb-4acc-9957-2b06d6267505' User entered 'No (N)'	System	17 Feb 2021 19:33:30
	System	17 Feb 2021 19:33:30

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

Have you been exposed to someone with 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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-02-17T14:33:19', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '1545c1a9-fbbb-4acc-9957-2b06d6267505' User entered 'No (N)'	System	17 Feb 2021 19:33:30

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-02-17T14:33:26', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '1545c1a9-fbbb-4acc-9957-2b06d6267505' User entered '17 Feb 2021 14:33:26'	System	17 Feb 2021 19:33:30
	System	17 Feb 2021 19:33:30

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-02-27T23:30:07-05:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd4b1ddac-e7b5-42fd-8211-5dbebe5efd47'	System	28 Feb 2021 04:30:26
User entered 'No (N)'	System	28 Feb 2021 04:30:26

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Have you been exposed to someone with 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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-02-27T23:30:13-05:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd4b1ddac-e7b5-42fd-8211-5dbebe5efd47'	System	28 Feb 2021 04:30:26
User entered 'No (N)'	System	28 Feb 2021 04:30:26



**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-02-27T23:30:24-05:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: 'd4b1ddac-e7b5-42fd-8211-5dbebe5efd47'	System	28 Feb 2021 04:30:26
User entered '27 Feb 2021 23:30:24'	System	28 Feb 2021 04:30:26

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-03-04T15:17:23-05:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '14aa6625-8cb6-42e1-acd2-fd5734c81de4'	System	04 Mar 2021 20:17:43
User entered 'No (N)'	System	04 Mar 2021 20:17:43

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

Have you been exposed to someone with 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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-03-04T15:17:29-05:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '14aa6625-8cb6-42e1-acd2-fd5734c81de4'	System	04 Mar 2021 20:17:43
User entered 'No (N)'	System	04 Mar 2021 20:17:43

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-03-04T15:17:36-05:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '14aa6625-8cb6-42e1-acd2-fd5734c81de4' User entered '04 Mar 2021 15:17:36'	System	04 Mar 2021 20:17:43
	System	04 Mar 2021 20:17:43

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 01:53:12



**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-03-11T20:14:02-05:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '50f085f9-5a85-4300-ba94-2ec09090a39c'	System	12 Mar 2021 01:14:20
User entered 'No (N)'	System	12 Mar 2021 01:14:20

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

Have you been exposed to someone with 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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-03-11T20:14:06-05:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '50f085f9-5a85-4300-ba94-2ec09090a39c'	System	12 Mar 2021 01:14:20
User entered 'No (N)'	System	12 Mar 2021 01:14:20

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-03-11T20:14:13-05:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '50f085f9-5a85-4300-ba94-2ec09090a39c'	System	12 Mar 2021 01:14:20
User entered '11 Mar 2021 20:14:13'	System	12 Mar 2021 01:14:20

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 01:53:12



**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-03-17T21:42:41-04:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '9cba800d-4092-4876-ad69-a721bd7294be' User entered 'No (N)'	System	18 Mar 2021 01:42:58
	System	18 Mar 2021 01:42:58

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

Have you been exposed to someone with 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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-03-17T21:42:47-04:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '9cba800d-4092-4876-ad69-a721bd7294be' User entered 'No (N)'	System	18 Mar 2021 01:42:58
	System	18 Mar 2021 01:42:58

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-03-17T21:42:55-04:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '9cba800d-4092-4876-ad69-a721bd7294be' User entered '17 Mar 2021 21:42:55'	System	18 Mar 2021 01:42:58
	System	18 Mar 2021 01:42:58

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-03-24T13:05:14-04:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '5985789b-f97e-4e62-80c7-0219ad217edc' User entered 'No (N)'	System	24 Mar 2021 17:08:41
	System	24 Mar 2021 17:08:41

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Have you been exposed to someone with 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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-03-24T13:05:19-04:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '5985789b-f97e-4e62-80c7-0219ad217edc' User entered 'No (N)'	System	24 Mar 2021 17:08:41
	System	24 Mar 2021 17:08:41



**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-03-24T13:05:25-04:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '5985789b-f97e-4e62-80c7-0219ad217edc' User entered '24 Mar 2021 13:05:25'	System	24 Mar 2021 17:08:41
	System	24 Mar 2021 17:08:41

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-03-31T15:56:49-04:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '5eb8c72c-7d5e-44e9-88af-b329f039fac4'	System	31 Mar 2021 19:57:02
User entered 'No (N)'	System	31 Mar 2021 19:57:02

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Have you been exposed to someone with 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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-03-31T15:56:53-04:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '5eb8c72c-7d5e-44e9-88af-b329f039fac4'	System	31 Mar 2021 19:57:02
User entered 'No (N)'	System	31 Mar 2021 19:57:02

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-03-31T15:56:59-04:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '5eb8c72c-7d5e-44e9-88af-b329f039fac4' User entered '31 Mar 2021 15:56:59'	System	31 Mar 2021 19:57:02
	System	31 Mar 2021 19:57:02

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 01:53:12



**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-04-07T08:27:14-04:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '55b511a1-316a-444b-9b1d-0e80c8e94b1c' User entered 'No (N)'	System	07 Apr 2021 12:27:29
	System	07 Apr 2021 12:27:29

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Have you been exposed to someone with 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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-04-07T08:27:20-04:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '55b511a1-316a-444b-9b1d-0e80c8e94b1c' User entered 'No (N)'	System	07 Apr 2021 12:27:29
	System	07 Apr 2021 12:27:29

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-04-07T08:27:27-04:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '55b511a1-316a-444b-9b1d-0e80c8e94b1c' User entered '07 Apr 2021 08:27:27'	System	07 Apr 2021 12:27:29
	System	07 Apr 2021 12:27:29

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 01:53:12



**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-04-14T16:46:36-04:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '7718e9a8-a29c-4f37-b40c-8bd608ad55a1' User entered 'No (N)'	System	14 Apr 2021 20:46:50
	System	14 Apr 2021 20:46:50

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Have you been exposed to someone with 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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-04-14T16:46:40-04:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '7718e9a8-a29c-4f37-b40c-8bd608ad55a1' User entered 'No (N)'	System	14 Apr 2021 20:46:50
	System	14 Apr 2021 20:46:50

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-04-14T16:46:45-04:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '7718e9a8-a29c-4f37-b40c-8bd608ad55a1' User entered '14 Apr 2021 16:46:45'	System	14 Apr 2021 20:46:50
	System	14 Apr 2021 20:46:50

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 01:53:12



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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-04-30T22:14:46-04:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '2ec04093-70d2-4fe1-92d4-4576ed984701'	System	01 May 2021 02:15:00
User entered 'No (N)'	System	01 May 2021 02:15:00

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Have you been exposed to someone with 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 (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-04-30T22:14:51-04:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '2ec04093-70d2-4fe1-92d4-4576ed984701'	System	01 May 2021 02:15:00
User entered 'No (N)'	System	01 May 2021 02:15:00

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-04-30T22:14:57-04:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '2ec04093-70d2-4fe1-92d4-4576ed984701'	System	01 May 2021 02:15:00
User entered '30 Apr 2021 22:14:57'	System	01 May 2021 02:15:00

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '05 May 2021 00:01'	System	20 Nov 2020 01:53:12



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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '09 May 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '12 May 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '16 May 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '19 May 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '23 May 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 01:53:12



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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '26 May 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '30 May 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '02 Jun 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '06 Jun 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '09 Jun 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '13 Jun 2021 23:59'	System	20 Nov 2020 01:53:12



**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '16 Jun 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '20 Jun 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '23 Jun 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '27 Jun 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '30 Jun 2021 00:01'	System	20 Nov 2020 01:53:12



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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '04 Jul 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '07 Jul 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '11 Jul 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '14 Jul 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '18 Jul 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 01:53:12



**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '21 Jul 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '25 Jul 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '28 Jul 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '01 Aug 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '04 Aug 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '08 Aug 2021 23:59'	System	20 Nov 2020 01:53:12



**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '11 Aug 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '15 Aug 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '18 Aug 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '22 Aug 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '25 Aug 2021 00:01'	System	20 Nov 2020 01:53:12



**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '29 Aug 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '01 Sep 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '05 Sep 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '08 Sep 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '12 Sep 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 01:53:12



**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '15 Sep 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '19 Sep 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '22 Sep 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '26 Sep 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '29 Sep 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '03 Oct 2021 23:59'	System	20 Nov 2020 01:53:12



**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '06 Oct 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '10 Oct 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '13 Oct 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '17 Oct 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '20 Oct 2021 00:01'	System	20 Nov 2020 01:53:12



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '24 Oct 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '27 Oct 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '31 Oct 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '03 Nov 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '07 Nov 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 01:53:12



**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '10 Nov 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '14 Nov 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '17 Nov 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '21 Nov 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '24 Nov 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '28 Nov 2021 23:59'	System	20 Nov 2020 01:53:12



**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '01 Dec 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '05 Dec 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '08 Dec 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '12 Dec 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '15 Dec 2021 00:01'	System	20 Nov 2020 01:53:12



**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '19 Dec 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '22 Dec 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '26 Dec 2021 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '29 Dec 2021 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '02 Jan 2022 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 01:53:12



**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '05 Jan 2022 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '09 Jan 2022 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '12 Jan 2022 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '16 Jan 2022 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '19 Jan 2022 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '23 Jan 2022 23:59'	System	20 Nov 2020 01:53:12



**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '26 Jan 2022 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '30 Jan 2022 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '02 Feb 2022 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '06 Feb 2022 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '09 Feb 2022 00:01'	System	20 Nov 2020 01:53:12



**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '13 Feb 2022 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '16 Feb 2022 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '20 Feb 2022 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '23 Feb 2022 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '27 Feb 2022 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 01:53:12



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '02 Mar 2022 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '06 Mar 2022 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '09 Mar 2022 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '13 Mar 2022 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '16 Mar 2022 00:01'	System	20 Nov 2020 01:53:12

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '20 Mar 2022 23:59'	System	20 Nov 2020 01:53:12



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '23 Mar 2022 00:01'	System	20 Nov 2020 01:53:12

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '27 Mar 2022 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '30 Mar 2022 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '03 Apr 2022 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '06 Apr 2022 00:01'	System	20 Nov 2020 01:53:12



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '10 Apr 2022 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '13 Apr 2022 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '17 Apr 2022 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '20 Apr 2022 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '24 Apr 2022 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 01:53:12



**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '27 Apr 2022 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '01 May 2022 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '04 May 2022 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '08 May 2022 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '11 May 2022 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '15 May 2022 23:59'	System	20 Nov 2020 01:53:12



**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '18 May 2022 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '22 May 2022 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '25 May 2022 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '29 May 2022 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '01 Jun 2022 00:01'	System	20 Nov 2020 01:53:12



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '05 Jun 2022 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '08 Jun 2022 00:01'	System	20 Nov 2020 01:53:12

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '12 Jun 2022 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '15 Jun 2022 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '19 Jun 2022 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 01:53:12



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '22 Jun 2022 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '26 Jun 2022 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '29 Jun 2022 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '03 Jul 2022 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '06 Jul 2022 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '10 Jul 2022 23:59'	System	20 Nov 2020 01:53:12



**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '13 Jul 2022 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '17 Jul 2022 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '20 Jul 2022 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '24 Jul 2022 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '27 Jul 2022 00:01'	System	20 Nov 2020 01:53:12



**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '31 Jul 2022 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '03 Aug 2022 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '07 Aug 2022 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '10 Aug 2022 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '14 Aug 2022 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 01:53:12



**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '17 Aug 2022 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '21 Aug 2022 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '24 Aug 2022 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '28 Aug 2022 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '31 Aug 2022 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '04 Sep 2022 23:59'	System	20 Nov 2020 01:53:12



**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '07 Sep 2022 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '11 Sep 2022 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '14 Sep 2022 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '18 Sep 2022 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '21 Sep 2022 00:01'	System	20 Nov 2020 01:53:12



**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '25 Sep 2022 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '28 Sep 2022 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '02 Oct 2022 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '05 Oct 2022 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '09 Oct 2022 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 01:53:12



**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '12 Oct 2022 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '16 Oct 2022 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '19 Oct 2022 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '23 Oct 2022 23:59'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '26 Oct 2022 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '30 Oct 2022 23:59'	System	20 Nov 2020 01:53:12



**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '02 Nov 2022 00:01'	System	20 Nov 2020 01:53:12

**US3672278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:25:56**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:53:12
Amendment Manager: User entered '06 Nov 2022 23:59'	System	20 Nov 2020 01:53:12

US3672278

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:25:56

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 02:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-02-27T23:30:40-05:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '64a56bdd-1826-44a7-a278-191f754c2cc6' User entered 'No (N)'	System	28 Feb 2021 04:30:57
	System	28 Feb 2021 04:30:57

**US3672278**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:26:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5ACDB0F-7495-466E-8F98-F8662404A66B)', Time: '2021-02-27T23:30:53-05:00', User OID: 'PatientReportedOutcome (US3672278)', ODM File OID: '64a56bdd-1826-44a7-a278-191f754c2cc6' User entered '27 Feb 2021 23:30:53'	System	28 Feb 2021 04:30:57
	System	28 Feb 2021 04:30:57

**US3672278**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:25:56**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:44:17

**US3672278**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:25:56**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '23 Nov 2020'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:44:17

US3672278

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:44:17



**US3672278**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:25:56**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:44:17

US3672278

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:44:32

**US3672278**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:25:56**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 21:22:09
User entered 'I'	System	23 Nov 2020 21:44:32

**US3672278**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:25:56**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:36:02
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Dec 2020 13:15:58

**US3672278**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:25:56**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:36:02
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '29 Dec 2020'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 13:15:58

**US3672278**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:25:56**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:36:02
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 13:15:58

**US3672278**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:25:56**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:36:02
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 13:15:58

US3672278

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:36:02
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Dec 2020 13:16:02



**US3672278**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:25:56**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:36:02
User entered 'I'	System	30 Dec 2020 13:16:02

US3672278

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:36:02
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
User closed query 'Per GCL Lab Recon: Immuno: Per GCL, there is an Immuno sample collected on 26 JAN 2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 04:47:20
Query 'Per GCL Lab Recon: Immuno: Per GCL, there is an Immuno sample collected on 26 JAN 2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 14:57:41
User opened query 'Per GCL Lab Recon: Immuno: Per GCL, there is an Immuno sample collected on 26 JAN 2021 for the Participant Decision Visit / OL-D1, however, there is no data recorded in the Patient Decision Visit / OL-D1 folder. Please clarify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 17:47:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 15:29:03

US3672278

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:56

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:36:02
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
User closed query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab (Single): Sample dated 26-Jan-2021 is reported under OL-1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 08:07:17
Query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab (Single): Sample dated 26-Jan-2021 is reported under OL-1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 14:57:47
User opened query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab (Single): Sample dated 26-Jan-2021 is reported under OL-1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 09:35:23
User entered '26 Jan 2021'	(b) (4), (b) (6)	27 Jan 2021 15:29:03

**US3672278**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:25:56**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:36:02
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:29:03

US3672278

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:56

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:36:02
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 15:29:03

US3672278

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:36:02
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 26JAN2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Else Clarify, Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 05:21:36
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 26JAN2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Else Clarify, Thank you' answered with 'listed' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 21:01:30
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 26JAN2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC as appropriate. Else Clarify, Thank you' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 13:11:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Jan 2021 15:29:07

**US3672278**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:25:56**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:36:02
User entered 'I'	System	27 Jan 2021 15:29:07

**US3672278**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:25:56**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:36:02
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 18:47:16



**US3672278**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:25:56**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:36:02
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '22 Feb 2021'	(b) (4), (b) (6)	22 Feb 2021 18:47:16

US3672278

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:25:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:36:02
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:47:16

**US3672278**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:25:56**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:36:02
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:47:16

**US3672278**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:25:56**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:36:02
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 18:47:21

**US3672278**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:25:56**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:36:02
User entered 'I'	System	22 Feb 2021 18:47:21

**US3672278**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:25:56**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:52
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 18:32:09

US3672278

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:25:56

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:52
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
	(b) (4)	
User entered '24 Mar 2021'	(b) (4), (b) (6)	24 Mar 2021 18:32:09

US3672278

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:25:56

[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 13:12:52
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	24 Mar 2021 18:32:09



**US3672278**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:25:56**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:52
User entered 'VISIT4'	System	24 Mar 2021 18:32:09

US3672278

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:52
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
User closed query 'Per CDM: Visit 4 Day 209 and Visit OL-D57 are both dated 17Mar2021. However, the data on the Vital Signs forms 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)	12 Apr 2021 16:19:53
Query 'Per CDM: Visit 4 Day 209 and Visit OL-D57 are both dated 17Mar2021. However, the data on the Vital Signs forms 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 'YES THEY DO. PLEASE DO NOT ISSUE QUERIES FOR THE SAKE OF ISSUING QUERIES. BOTH FORMS SAY VITALS ARE NOT DONE.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 22:48:59
User opened query 'Per CDM: Visit 4 Day 209 and Visit OL-D57 are both dated 17Mar2021. However, the data on the Vital Signs forms 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)	05 Apr 2021 20:30:41
User entered 'No (N)'	(b) (4), (b) (6)	31 Mar 2021 20:04:52

US3672278

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:52
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 20:04:52

US3672278

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:56

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:52
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 20:04:52

**US3672278**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:25:56**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:52
User entered empty.	System	31 Mar 2021 20:04:52

US3672278

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:52
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 20:04:52

US3672278

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:52
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 20:04:52

**US3672278**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:25:56**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:52
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 20:04:52



US3672278

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:52
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 20:04:52

**US3672278**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:25:56**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:52
User entered empty.	System	31 Mar 2021 20:04:52

US3672278

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:52
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 20:04:52

US3672278

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:52
User entered empty.	System	31 Mar 2021 20:04:52

US3672278

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:52
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 20:04:52

**US3672278**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:25:56**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:52
User entered empty.	System	31 Mar 2021 20:04:52

US3672278

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:52
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 20:04:52

US3672278

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:52
User entered empty.	System	31 Mar 2021 20:04:52



**US3672278**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:25:56**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:52

US3672278

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:56

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:52

US3672278

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:25:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:52
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	24 Mar 2021 18:32:14

US3672278

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:25:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:52
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 18:32:14

US3672278

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:25:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:52
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 18:32:24

US3672278

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:25:56

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:52
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
	(b) (4)	
User entered '24 Mar 2021'	(b) (4), (b) (6)	24 Mar 2021 18:32:24

US3672278

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:25:56

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:52
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Mar 2021 18:42:13
User entered '14:25' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 18:42:13
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Mar 2021 18:32:24
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 18:32:24

**US3672278**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:25:56**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:52
User entered '24 Mar 2021 14:25'	System	24 Mar 2021 18:42:13
User entered empty.	System	24 Mar 2021 18:32:24



US3672278

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:52
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 18:32:31

**US3672278**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:25:56**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:12:52
User entered '1'	System	24 Mar 2021 18:32:31

**US3672278**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:25:56**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:21:24

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:25:56

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:21:24

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:25:56

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:21:24

**US3672278**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:25:56**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User entered 'UNBLND_DECIDE'	System	25 Feb 2021 16:21:24

**US3672278**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:25:56**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:22:41

**US3672278**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:25:56**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:31:32



**US3672278**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:25:56**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:22:41

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:25:56

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
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 field.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 14:55:04
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 field.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 18:48:09
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 18:47:51
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 field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 15:10:09
User entered 'AMENDMENT 5 (AMENDMENT 5)'	System	10 Mar 2021 16:55:28
WR# 5295537		
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:31:32

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:25:56

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:22:41

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:25:56

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	25 Feb 2021 16:22:41

**US3672278**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:25:56**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	25 Feb 2021 16:22:41

**US3672278**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:25:56**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Not Administered (NA)'	(b) (4), (b) (6)	25 Feb 2021 16:22:41

**US3672278**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:25:56**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:22:41

**US3672278**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:25:56**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User entered '1'	System	25 Feb 2021 16:22:41



**US3672278**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:25:56**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User entered 'I'	System	25 Feb 2021 16:22:41

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:25:56

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:23:44

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:25:56

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:23:44

**US3672278**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:25:56**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User entered empty.	System	25 Feb 2021 16:23:44
DataPoint set to visible.	System	25 Feb 2021 16:22:41

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:25:56

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:23:44

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:25:56

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:23:44

**US3672278**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:25:56**

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User entered empty.	System	25 Feb 2021 16:23:44
DataPoint set to visible.	System	25 Feb 2021 16:22:41

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	25 Feb 2021 16:23:44



US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:23:44

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:23:44

**US3672278**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:25:56**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '12:00'	(b) (4), (b) (6)	25 Feb 2021 16:23:44

**US3672278**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User entered '26 Jan 2021 12:00'	System	25 Feb 2021 16:23:44

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '98.7' F	(b) (4), (b) (6)	25 Feb 2021 16:23:44

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:23:44

**US3672278**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:25:56**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:23:44

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '62'	(b) (4), (b) (6)	25 Feb 2021 16:23:44



**US3672278**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User entered 'bpm'	System	25 Feb 2021 16:23:44

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '13'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:23:44

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User entered 'breaths/min'	System	25 Feb 2021 16:23:44

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '105'	(b) (4), (b) (6)	25 Feb 2021 16:23:44

**US3672278**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User entered 'mmHg'	System	25 Feb 2021 16:23:44

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User closed query 'Per CDM: Response noted. Please indicate if CS/NCS and report as AE, if applicable. Thank you ' (Site from DM).	(b) (4)	05 Mar 2021 12:33:05
Query 'Per CDM: Response noted. Please indicate if CS/NCS and report as AE, if applicable. Thank you ' answered with 'NCS' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 20:38:46
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	26 Feb 2021 11:33:30
User opened query 'Per CDM: Response noted. Please indicate if CS/NCS and report as AE, if applicable. Thank you ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 11:33:28
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'GRADE 0 please advise ' (Site from System).	(b) (4), (b) (6)	25 Feb 2021 16:24:19
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		25 Feb 2021 16:23:44
User entered '59'	(b) (4), (b) (6)	25 Feb 2021 16:23:44

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User entered 'mmHg'	System	25 Feb 2021 16:23:44

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:25:56

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered missing code ND - Not Done.	(b) (4), (b) (6)	25 Feb 2021 16:23:44



**US3672278**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:25:56**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:23:44

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:25:56

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User entered empty.	System	25 Feb 2021 16:23:44
DataPoint set to visible.	System	25 Feb 2021 16:22:41

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	25 Feb 2021 16:27:20

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:27:20

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:27:20

**US3672278**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:25:56**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '12:56'	(b) (4), (b) (6)	25 Feb 2021 16:27:20

**US3672278**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:25:56**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User entered '26 Jan 2021 12:56'	System	25 Feb 2021 16:27:20

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '98.4' F	(b) (4), (b) (6)	25 Feb 2021 16:27:20



US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:27:20

**US3672278**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:25:56**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:27:20

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '61'	(b) (4), (b) (6)	25 Feb 2021 16:27:20

**US3672278**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:25:56**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User entered 'bpm'	System	25 Feb 2021 16:27:20

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '14'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:27:20

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User entered 'breaths/min'	System	25 Feb 2021 16:27:20

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '109'	(b) (4), (b) (6)	25 Feb 2021 16:27:20

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User entered 'mmHg'	System	25 Feb 2021 16:27:20



US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '65'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:27:20

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User entered 'mmHg'	System	25 Feb 2021 16:27:20

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:25:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:24:33

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:25:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:24:33

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:56

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:24:54

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:56

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 16:24:54

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:56

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 16:24:54

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:56

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User entered 'mRNA-1273'	System	25 Feb 2021 16:24:54
DataPoint set to visible.	System	25 Feb 2021 16:22:41



US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:56

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:24:54

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:56

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '12:22'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:24:54

**US3672278**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:25:56**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User entered '26 Jan 2021 12:22'	System	25 Feb 2021 16:24:54

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:56

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:24:54

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:56

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User entered 'ONCE'	System	25 Feb 2021 16:24:54

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:56

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User entered 'INTRAMUSCULAR'	System	25 Feb 2021 16:24:54

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:25:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:25:51

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:25:56

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:25:51



**US3672278**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:25:56**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '12:09'	(b) (4), (b) (6)	25 Feb 2021 16:25:51

**US3672278**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:25:56**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User entered '26 Jan 2021 12:09'	System	25 Feb 2021 16:25:51

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:25:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:26:16

**US3672278**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:25:56**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:26:16

**US3672278**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:25:56**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '11:55'	(b) (4), (b) (6)	25 Feb 2021 16:26:16

**US3672278**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:25:56**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User entered '26 Jan 2021 11:55'	System	25 Feb 2021 16:26:16

US3672278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:25:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:26:23

**US3672278**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:25:56**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:00:14
User entered 'I'	System	25 Feb 2021 16:26:23



**US3672278**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:25:56**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:56
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Feb 2021 16:28:24

**US3672278**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:25:56**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:56
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '05 Feb 2021'	(b) (4), (b) (6)	25 Feb 2021 16:28:24

**US3672278**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:25:56**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:56
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	25 Feb 2021 16:28:24

**US3672278**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:25:56**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:56
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 16:28:24

**US3672278**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:25:56**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:56
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Feb 2021 16:28:29

**US3672278**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:25:56**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:56
User entered 'I'	System	25 Feb 2021 16:28:29

**US3672278**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:25:56**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:45:56
User entered '1'	System	25 Feb 2021 16:28:29
DataPoint set to visible.	System	25 Feb 2021 16:28:29

**US3672278**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:25:56**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:28:39



**US3672278**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:25:56**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:28:39

**US3672278**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:25:56**

[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 23:01:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:28:39

**US3672278**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:25:56**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User entered 'OLD29'	System	25 Feb 2021 16:28:39

**US3672278**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	25 Feb 2021 16:29:28

**US3672278**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:29:28

**US3672278**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:29:28

**US3672278**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:25:56**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '10:44'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:29:28

**US3672278**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User entered '24 Feb 2021 10:44'	System	25 Feb 2021 16:29:28



US3672278

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:29:28

US3672278

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:29:28

**US3672278**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:25:56**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:29:28

**US3672278**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '61'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:29:28

**US3672278**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User entered 'bpm'	System	25 Feb 2021 16:29:28

US3672278

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '16'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:29:28

US3672278

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User entered 'breaths/min'	System	25 Feb 2021 16:29:28

**US3672278**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '109'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:29:28



**US3672278**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User entered 'mmHg'	System	25 Feb 2021 16:29:28

US3672278

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:25:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	26 Feb 2021 11:36:04
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4), (b) (6)	25 Feb 2021 16:29:44
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		25 Feb 2021 16:29:28
User entered '57'	(b) (4), (b) (6)	25 Feb 2021 16:29:28

**US3672278**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User entered 'mmHg'	System	25 Feb 2021 16:29:28

US3672278

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	25 Feb 2021 16:30:20

**US3672278**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:25:56**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:30:20

**US3672278**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:25:56**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:30:20

**US3672278**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:25:56**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '11:48'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:30:20

**US3672278**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:25:56**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User entered '24 Feb 2021 11:48'	System	25 Feb 2021 16:30:20



US3672278

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:30:20

**US3672278**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:25:56**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:30:20

**US3672278**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:25:56**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:30:20

**US3672278**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:25:56**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '60'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:30:20

**US3672278**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:25:56**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User entered 'bpm'	System	25 Feb 2021 16:30:20

US3672278

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '15'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:30:20

US3672278

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User entered 'breaths/min'	System	25 Feb 2021 16:30:20

US3672278

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '103'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:30:20



**US3672278**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:25:56**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User entered 'mmHg'	System	25 Feb 2021 16:30:20

US3672278

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	05 Mar 2021 12:32:42
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	(b) (4), (b) (6)	04 Mar 2021 13:49:13
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		25 Feb 2021 16:30:20
User entered '59'	(b) (4), (b) (6)	25 Feb 2021 16:30:20

US3672278

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:25:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User entered 'mmHg'	System	25 Feb 2021 16:30:20

**US3672278**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:25:56**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:30:28

**US3672278**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:25:56**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:30:28

**US3672278**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:25:56**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:31:03

**US3672278**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:25:56**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:31:03

US3672278

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:56

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 23:01:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered empty.	(b) (4), (b) (6)	25 Feb 2021 16:31:03



**US3672278**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:25:56**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User entered 'mRNA-1273'	System	25 Feb 2021 16:31:03
DataPoint set to visible.	System	25 Feb 2021 16:28:29

US3672278

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:56

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:31:03

**US3672278**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:25:56**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '11:10'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:31:03

**US3672278**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:25:56**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User entered '24 Feb 2021 11:10'	System	25 Feb 2021 16:31:03

US3672278

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:25:56

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:31:03

**US3672278**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:25:56**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User entered 'ONCE'	System	25 Feb 2021 16:31:03

**US3672278**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:25:56**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User entered 'INTRAMUSCULAR'	System	25 Feb 2021 16:31:03

**US3672278**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:25:56**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 16:31:07



**US3672278**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:25:56**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:01:51
User entered 'I'	System	25 Feb 2021 16:31:07

**US3672278**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:25:56**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:35
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:11:18

**US3672278**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:25:56**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:35
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
User entered '3 Mar 2021'	(b) (4), (b) (6)	09 Mar 2021 21:11:18

**US3672278**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:25:56**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:35
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Mar 2021 21:11:18

**US3672278**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:25:56**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:35
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:11:18

**US3672278**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:25:56**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:35
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 21:11:22

**US3672278**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:25:56**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:40:35
User entered 'I'	System	09 Mar 2021 21:11:22

**US3672278**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:25:56**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:38:48
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 18:30:46



**US3672278**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:25:56**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:38:48
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:30:46

**US3672278**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:25:56**

[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 05:38:48
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:30:46

**US3672278**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:25:56**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:38:48
User entered 'OLD57'	System	24 Mar 2021 18:30:46

**US3672278**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:25:56**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:38:48
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:31:38

**US3672278**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:25:56**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:38:48
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:31:38

**US3672278**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:25:56**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:38:48
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
User entered '14:11'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:31:38

**US3672278**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:25:56**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:38:48
User entered '24 Mar 2021 14:11'	System	24 Mar 2021 18:31:38

**US3672278**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:25:56**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:38:48
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
User entered '98.6' F	(b) (4), (b) (6)	24 Mar 2021 18:31:38



**US3672278**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:25:56**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:38:48
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:31:38

**US3672278**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:25:56**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:38:48
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:31:38

**US3672278**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:25:56**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:38:48
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
User entered '72'	(b) (4), (b) (6)	24 Mar 2021 18:31:38

**US3672278**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:25:56**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:38:48
User entered 'bpm'	System	24 Mar 2021 18:31:38

US3672278

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:25:56

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:38:48
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
User entered '12'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:31:38

**US3672278**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:25:56**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:38:48
User entered 'breaths/min'	System	24 Mar 2021 18:31:38

**US3672278**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:25:56**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:38:48
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
User entered '110'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:31:38

**US3672278**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:25:56**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:38:48
User entered 'mmHg'	System	24 Mar 2021 18:31:38



**US3672278**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:25:56**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:38:48
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
User entered '84'	(b) (4), (b) (6)	24 Mar 2021 18:31:38

**US3672278**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:25:56**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:38:48
User entered 'mmHg'	System	24 Mar 2021 18:31:38

**US3672278**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:25:56**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:38:48

**US3672278**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:25:56**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:38:48

**US3672278**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:25:56**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:38:48
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:31:45

**US3672278**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:25:56**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:38:48
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:31:45

**US3672278**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:25:56**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:38:48
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:31:53

US3672278

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:25:56

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:38:48
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
User entered '24 Mar 2021'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 18:31:53



US3672278

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:25:56

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:38:48
User signature succeeded.	Cynthia Strout (b) (4)	16 Apr 2021 15:17:21
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
User entered '14:25' reason for change: Data Entry Error	System	24 Mar 2021 18:42:37
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	24 Mar 2021 18:42:37
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	24 Mar 2021 18:31:53
	(b) (4), (b) (6)	24 Mar 2021 18:31:53

**US3672278**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:25:56**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:38:48
User entered '24 Mar 2021 14:25'	System	24 Mar 2021 18:42:37
User entered empty.	System	24 Mar 2021 18:31:53

**US3672278**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 10 Jun 2021 09:25:56**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:06:34
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:59:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 18:57:30

**US3672278**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:25:56**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 13:05:39
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:01
User entered	System	12 Sep 2020 19:18:32
'USA-US116-2020-mRNA-1273-P301000001'		
User entered 'New'	(b) (4), (b) (6)	12 Sep 2020 19:18:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:56

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User closed query 'PV Query:: Please specify type of stroke the subject experienced (i.e. ischemic, hemorrhagic)' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 16:29:03
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Ischaemic stroke, LLT: Ischemic stroke - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 23:03:22
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 23:03:22
	(b) (4)	
Query 'PV Query:: Please specify type of stroke the subject experienced (i.e. ischemic, hemorrhagic)' answered with 'type of stroke updated' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 16:48:40
Data point term sent to Coder	System	22 Oct 2020 16:48:26
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 16:48:23
Coding entries removed.	(b) (4), (b) (6)	22 Oct 2020 16:48:23
User entered 'ischemic STROKE (frontal lobe)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 16:48:23
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 13:05:42
User opened query 'PV Query:: Please specify type of stroke the subject experienced (i.e. ischemic, hemorrhagic)' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 19:55:25
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: Stroke - version MedDRA\23.0.	Coder Import (b) (4)	16 Sep 2020 11:20:39
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	16 Sep 2020 11:20:39
	(b) (4)	
Data point term sent to Coder	System	11 Sep 2020 19:00:33
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 19:00:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:56

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 19:00:04
User entered 'Frontal Lobe Stroke' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 19:00:04
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 18:59:22
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 18:59:22

**US3672278**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 13:05:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 18:59:22

**US3672278**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 13:05:44
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 18:59:22



**US3672278**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 13:05:46
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 18:59:22

**US3672278**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 13:05:49
User entered '10 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 18:59:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:56

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:30:25
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	11 Sep 2020 19:00:29
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Sep 2020 19:00:29
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 19:00:29
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Sep 2020 18:59:22
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	11 Sep 2020 18:59:22
User entered 'un:un' (non-conformant).	(b) (4), (b) (6)	11 Sep 2020 18:59:22

**US3672278**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:25:56**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 19:00:29
User entered '10 Sep 2020 UN:UN' (non-conformant).	System	11 Sep 2020 18:59:22

**US3672278**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:23:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 21:04:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 18:59:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:23:26
User entered '11 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 21:04:52
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 18:59:22

**US3672278**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:25:56**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:23:28
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 18:59:22

**US3672278**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:25:56**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 19:39:43
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 19:54:44
User entered empty.	System	11 Sep 2020 18:59:22



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:56

Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:57:42
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User closed query 'PV Query: Please confirm intensity of grade 3 as events resulted in hospitalization, and consider upgrading to grade 4.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 14:46:39
Query 'PV Query: Please confirm intensity of grade 3 as events resulted in hospitalization, and consider upgrading to grade 4.' answered with 'Severity recorded as Grade 3 in error, correction made.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 20:09:05
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 20:08:47
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 20:08:47
User opened query 'PV Query: Please confirm intensity of grade 3 as events resulted in hospitalization, and consider upgrading to grade 4.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 17:37:53
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:25:49
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 19:09:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 19:09:29
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 19:09:29
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 18:59:22
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 18:59:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:26:50
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 19:00:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 19:00:04
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 19:00:04
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 18:59:22
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 18:59:22

**US3672278**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 18:59:22

**US3672278**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 18:59:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:30:25
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)	23 Oct 2020 16:29:17
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 'last covid test was completed in office and subject results were negative' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 16:49:11
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 Sep 2020 19:54:59
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		11 Sep 2020 19:00:04
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		11 Sep 2020 19:00:04
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 19:00:04
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	11 Sep 2020 18:59:22
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 18:59:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:56

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered '10 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 18:59:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:56

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 18:59:22

**US3672278**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 18:59:22



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 18:59:22

US3672278

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 18:59:22

**US3672278**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 18:59:22

**US3672278**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 18:59:22

**US3672278**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	11 Sep 2020 18:59:22

**US3672278**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	11 Sep 2020 18:59:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:56

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User closed query 'Per CDM: The reason provided for study treatment not given on Exposure (V2D29) page is 'Physician withheld dose due to Adverse Event' however, 'none' is recorded here. Please confirm the 'Action taken with investigational product' again and update it appropriately or else clarify. Thank you ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 09:35:27
Query 'Per CDM: The reason provided for study treatment not given on Exposure (V2D29) page is 'Physician withheld dose due to Adverse Event' however, 'none' is recorded here. Please confirm the 'Action taken with investigational product' again and update it appropriately or else clarify. Thank you ' answered with 'corrected' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 20:01:16
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 20:01:11
User opened query 'Per CDM: The reason provided for study treatment not given on Exposure (V2D29) page is 'Physician withheld dose due to Adverse Event' however, 'none' is recorded here. Please confirm the 'Action taken with investigational product' again and update it appropriately or else clarify. Thank you ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 05:31:01
User entered 'None (NONE)'	(b) (4), (b) (6)	11 Sep 2020 18:59:22

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:25:56**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 18:59:22



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe (i.e., PLAVIX per SAE Narrative). Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 23:57:40
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe (i.e., PLAVIX per SAE Narrative). Please review and add a Con Medication as appropriate or update action taken.' answered with 'all conmeds related to event listed' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 16:51:56
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe (i.e., PLAVIX per SAE Narrative). Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 11:34:39
User entered 'I'	(b) (4), (b) (6)	11 Sep 2020 18:59:22

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 18:59:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:56

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 17:13:57
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'RESOLVED WITH SEQUAIE- AE of speech deficit.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 21:05:02
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 21:04:52
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 16:54:37
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 16:29:25
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'still resolving' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 16:51:45
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 19:54:32
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	11 Sep 2020 18:59:22

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Form: Adverse Events (1)

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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 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	30 Oct 2020 21:05:16
User entered 'AE of speech deficit' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 21:05:16
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	30 Oct 2020 21:04:52
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 18:59:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:56

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User closed query 'Per DM CLR: Narrative indicates that the subject had Speech Therapy, CT Brain, & Ultrasound Carotid Duplex. However, there are no corresponding Concomitant Procedures record that match these information. Please update to record the corresponding procedures as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 03:49:18
Query 'Per DM CLR: Narrative indicates that the subject had Speech Therapy, CT Brain, & Ultrasound Carotid Duplex. However, there are no corresponding Concomitant Procedures record that match these information. Please update to record the corresponding procedures as appropriate. Otherwise, clarify.' answered with 'Updated. Speech therapy is not a "procedure/surgery" - so I did not add. ' (Site from DM).	Patty Howenstine (b) (4)	24 Feb 2021 17:41:45
User opened query 'Per DM CLR: Narrative indicates that the subject had Speech Therapy, CT Brain, & Ultrasound Carotid Duplex. However, there are no corresponding Concomitant Procedures record that match these information. Please update to record the corresponding procedures as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Nov 2020 14:54:52
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User closed query 'Per DM CLR Re-query: Response noted However, ONGOING SPEECH DEFICIT AE has not been added in AE eCRF. Please review and confirm if this should be recorded as a separate entry in the AE eCRF. If 'Yes' update accordingly or clarify.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 05:56:54
Query 'Per DM CLR Re-query: Response noted However, ONGOING SPEECH DEFICIT AE has not been added in AE eCRF. Please review and confirm if this should be recorded as a separate entry in the AE eCRF. If 'Yes' update accordingly or clarify.' answered with 'ongoing speech deficit added to adverse events' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 16:50:01

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:56

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR Re-query: Response noted However, ONGOING SPEECH DEFICIT AE has not been added in AE eCRF. Please review and confirm if this should be recorded as a separate entry in the AE eCRF. If 'Yes' update accordingly or clarify.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 17:44:43
User closed query 'Per DM CLR: SAE NARRATIVE: ONGOING SPEECH DEFICIT. Please review and confirm if this should be recorded as a separate entry in the AE eCRF. If yes, please update AE eCRF. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 17:44:43
User closed query 'Per DM CLR: SAE NARRATIVE: Patient had MH of CVD, Plavix was started and will be starting speech therapy. Please review and ensure that these information were recorded in the appropriate eCRFs.' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 17:38:41
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e.head CT/MRI, carotid ultrasound, etc). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	28 Oct 2020 15:03:44
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e.head CT/MRI, carotid ultrasound, etc). Please include units and reference ranges if applicable.' answered with 'ADDED RELEVANT LAB AND DIAGNOSTIC TEST RESULTS. PLEASE LET US KNOW IF MORE INFORMATION IS NECESSARY AND WE CAN REQUEST IT.' (Site from Safety).	(b) (4), (b) (6)	27 Oct 2020 20:18:49

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT IS A 78 YEAR OLD MAKE WITH HISTORY OF CVD, CAD, CHF, AND DM. DAY 8 PHONE CALL WAS MADE ON 9/11/2020 AND WAS MOSTLY COMPLETED WITH SUBJECT'S WIFE. SUBJECT'S WIFE REPORTS ON 9/10/2020. SUBJECT DEVELOPED INABILITY TO SPEAK. HE WAS ADMITTED TO THE HOSPITAL AND DIAGNOSED WITH FRONTAL LOBE STROKE. SUBJECT WAS DISCHARGED 9/11/2020 WITH ONGOING SPEECH DEFICIT. HE WAS STARTED ON PLAVIX AND WILL BE STARTING SPEECH THERAPY. MEDICAL RECORDS WERE RECEIVED WHICH INCLUDED LAB RESULTS AND DIAGNOSTIC TEST RESULTS. RELEVANT OR ABNORMAL LAB TESTS INCLUDE: PTT 28.7 SEC, PT 13.4 SEC, INR 1.0, HGA1C 7.7%. FINDINGS FROM NONCONTRAST BRAIN CT SCAN ON 09/10/20 @ 1538 INLCUDE SMALL EVOLVING ACUTE INFARCTIONS IN THE LEFT INSULAR CORTEX AND ANTERIOR LEFT CORONA RADIATA, AND NO HEMORRHAGE. ULTRASOUND CAROTID DUPLEX BILATERAL COMPLETED ON 09/10/20 @ 1840 SHOWED NO STENOSIS BILATERALLY.' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 20:18:17
Query 'Per DM CLR: SAE NARRATIVE: ONGOING SPEECH DEFICIT. Please review and confirm if this should be recorded as a separate entry in the AE eCRF. If yes, please update AE eCRF. Otherwise, clarify.' answered with 'added' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 20:00:56
Query 'Per DM CLR: SAE NARRATIVE: Patient had MH of CVD, Plavix was started and will be starting speech therapy. Please review and ensure that these information were recorded in the appropriate eCRFs.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 20:00:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:25:56

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE NARRATIVE: ONGOING SPEECH DEFICIT. Please review and confirm if this should be recorded as a separate entry in the AE eCRF. If yes, please update AE eCRF. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 11:35:11
User opened query 'Per DM CLR: SAE NARRATIVE: Patient had MH of CVD, Plavix was started and will be starting speech therapy. Please review and ensure that these information were recorded in the appropriate eCRFs.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 11:34:51
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (i.e.head CT/MRI, carotid ultrasound, etc). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 19:55:08
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	11 Sep 2020 19:04:35
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	11 Sep 2020 19:04:35
User entered 'Subject is a 78 year old make with history of CVD, CAD, CHF, and DM. Day 8 Phone call was made on 9/11/2020 and was mostly completed with subject's wife. Subject's wife reports on 9/10/2020. Subject developed inability to speak. He was admitted to the hospital and diagnosed with frontal lobe stroke. Subject was discharged 9/11/2020 with ongoing speech deficit. He was started on plavix and will be starting speech therapy. Medical Records will be requested.' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Sep 2020 19:04:35
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	11 Sep 2020 19:00:04
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 18:59:22



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 19:00:04

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Sep 2020 18:59:22

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Sep 2020 18:59:22

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:25:56**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 17:15:42
User entered	(b) (4), (b) (6)	02 Nov 2020 17:15:34
'USA-US116-2020-mRNA-1273-P301000001'		

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:56

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User coded data point as SOC: Nervous system disorders, HLT: Neurological disorders NEC, HLT: Speech and language abnormalities, PT: Speech disorder, LLT: Speech disorder - version MedDRA\23.0.	Coder Import (b) (4)	30 Oct 2020 22:33:04
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	30 Oct 2020 22:33:04
Data point term sent to Coder	System	30 Oct 2020 21:06:21
Coding entries removed.	(b) (4), (b) (6)	30 Oct 2020 21:05:59
User entered 'SPEECH DEFICIT' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 21:05:59
User coded data point as SOC: Nervous system disorders, HLT: Neurological disorders NEC, HLT: Speech and language abnormalities, PT: Speech disorder, LLT: Speech disorder - version MedDRA\23.0.	Coder Import (b) (4)	30 Oct 2020 16:59:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	30 Oct 2020 16:59:56
Data point term sent to Coder	System	30 Oct 2020 16:46:32
User entered 'Ongoing speech deficit'	(b) (4), (b) (6)	30 Oct 2020 16:45:45

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:25:56**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 16:45:45

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:25:56**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered 'No (N)'	(b) (4), (b) (6)	30 Oct 2020 16:45:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered 'No (N)'	(b) (4), (b) (6)	30 Oct 2020 16:45:45



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:25:56**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered '10 Sep 2020'	(b) (4), (b) (6)	30 Oct 2020 16:45:45

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:25:56**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 16:45:45

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:25:56**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 16:45:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:57:20
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User closed query 'Per MM, Please provide end date and final outcome when available. ' (Site from DM).	(b) (4)	
Query 'Per MM, Please provide end date and final outcome when available. ' answered with 'done' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 15:50:08
DataPoint Un-verified.	Patty Howenstine (b) (4)	24 Feb 2021 17:42:43
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Patty Howenstine (b) (4)	24 Feb 2021 17:42:36
	(b) (4)	
User opened query 'Per MM, Please provide end date and final outcome when available. ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 11:35:47
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 16:45:45

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Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:57:22
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Un-verified.	Patty Howenstine (b) (4)	24 Feb 2021 17:42:36
User entered '26 Jan 2021' reason for change: Data Entry Error	Patty Howenstine (b) (4)	24 Feb 2021 17:42:36
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave this query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 14:46:53
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave this query open until information is available.' answered with 'Speech deficit still ongoing. Should site add Speech deficit to medical history considering it is now a chronic condition?' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 20:10:02
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. Please leave this query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 17:36:38
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 23:39:25
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'confirm ongoing' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 21:01:20
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 13:42:26

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 16:45:45

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 16:45:45

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:25:56**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 16:45:45



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	30 Oct 2020 16:45:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:30:25
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	30 Oct 2020 16:46:55
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	30 Oct 2020 16:45:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 16:45:45

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:25:56**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 16:45:45

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:25:56**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 16:45:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	30 Oct 2020 16:47:10
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		30 Oct 2020 16:47:10
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 16:47:10
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	30 Oct 2020 16:46:55
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 16:45:45

**US3672278**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:25:56**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered '10 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 16:46:55
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 16:45:45

US3672278

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:56

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered '11 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 16:46:55
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 16:45:45

**US3672278**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:25:56**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 16:46:55
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 16:45:45



**US3672278**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:25:56**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 16:45:45

US3672278

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 16:46:55
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 16:45:45

**US3672278**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:25:56**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 16:45:45

**US3672278**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:25:56**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 16:45:45

**US3672278**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:25:56**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	30 Oct 2020 16:45:45

**US3672278**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:25:56**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	30 Oct 2020 16:45:45

**US3672278**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:25:56**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 16:48:01
User entered 'None (NONE)'	(b) (4), (b) (6)	30 Oct 2020 16:45:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:56

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4) System	24 Feb 2021 17:43:55
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	24 Feb 2021 17:42:59
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 16:45:45



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:57:27
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'Updated' (Site from DM).	Patty Howenstine (b) (4)	24 Feb 2021 17:43:04
DataPoint Un-verified.	(b) (4)	
User entered '0' reason for change: Data Entry Error	Patty Howenstine (b) (4)	24 Feb 2021 17:42:59
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered '1'	(b) (4), (b) (6)	30 Oct 2020 16:45:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:57:29
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.' (Site from DM). Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.' answered with 'will add' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 18:35:49
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update response to this field.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 14:45:18
User signature succeeded.	(b) (4), (b) (6)	19 Mar 2021 11:44:02
DataPoint Un-verified.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '1' reason for change: Data Entry Error	Patty Howenstine (b) (4)	24 Feb 2021 17:43:55
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 16:45:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:56

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:57:32
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Patty Howenstine (b) (4)	24 Feb 2021 17:42:36
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 14:46:58
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Subject's speech is still currently affected' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 20:10:48
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 20:10:22
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 20:10:22
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 17:36:56
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:18:31
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 18:03:18
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 23:39:35
Query 'Data is required. Please complete.' answered with 'see previous query' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 21:01:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:56

[Outcome](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety). User opened query 'Data is required. Please complete.' (Site from System). DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 21:00:55
User entered empty; reason for change Data Entry Error	System	11 Nov 2020 21:00:41
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 21:00:41
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	11 Nov 2020 21:00:41
	(b) (4), (b) (6)	09 Nov 2020 13:42:44
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
	(b) (4), (b) (6)	30 Oct 2020 16:45:45

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:25:56**

[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 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 16:45:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:56

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative = BRAIN CT SCAN ON 09/10/20. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 18:37:33
User closed query 'Per DM CLR: Narrative = RELEVANT OR ABNORMAL LAB TESTS INCLUDE: PTT 28.7 SEC, PT 13.4 SEC, INR 1.0, HGA1C 7.7%. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 18:37:31
User closed query 'Per DM CLR: Narrative = WILL BE STARTING SPEECH THERAPY. Please review and verify if this was started. If yes, ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 18:37:13
Query 'Per DM CLR: Narrative = WILL BE STARTING SPEECH THERAPY. Please review and verify if this was started. If yes, ensure that this is captured in the appropriate eCRF. ' answered with 'will add' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 14:54:52
Query 'Per DM CLR: Narrative = BRAIN CT SCAN ON 09/10/20. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'will add' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 14:47:29
Query 'Per DM CLR: Narrative = RELEVANT OR ABNORMAL LAB TESTS INCLUDE: PTT 28.7 SEC, PT 13.4 SEC, INR 1.0, HGA1C 7.7%. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'will add' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 14:47:21
User opened query 'Per DM CLR: Narrative = BRAIN CT SCAN ON 09/10/20. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 11:43:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:56

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = RELEVANT OR ABNORMAL LAB TESTS INCLUDE: PTT 28.7 SEC, PT 13.4 SEC, INR 1.0, HGA1C 7.7%. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 11:43:52
User opened query 'Per DM CLR: Narrative = WILL BE STARTING SPEECH THERAPY. Please review and verify if this was started. If yes, ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 11:43:47
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User closed query 'Per DM CLR: Narrative indicates that subject had NONCONTRAST BRAIN CT SCAN & ULTRASOUND CAROTID DUPLEX. However, these are not recorded in the Concomitant Procedure eCRF. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 03:49:59
Query 'Per DM CLR: Narrative indicates that subject had NONCONTRAST BRAIN CT SCAN & ULTRASOUND CAROTID DUPLEX. However, these are not recorded in the Concomitant Procedure eCRF. ' answered with 'Updated procedures' (Site from DM).	Patty Howenstine (b) (4)	24 Feb 2021 17:43:11
User opened query 'Per DM CLR: Narrative indicates that subject had NONCONTRAST BRAIN CT SCAN & ULTRASOUND CAROTID DUPLEX. However, these are not recorded in the Concomitant Procedure eCRF. ' (Site from DM).	(b) (4), (b) (6)	12 Dec 2020 03:44:54
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:30:25
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	30 Oct 2020 16:48:01
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	30 Oct 2020 16:48:01

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:25:56

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT IS A 78 YEAR OLD MAKE WITH HISTORY OF CVD, CAD, CHF, AND DM. DAY 8 PHONE CALL WAS MADE ON 9/11/2020 AND WAS MOSTLY COMPLETED WITH SUBJECT'S WIFE. SUBJECT'S WIFE REPORTS ON 9/10/2020. SUBJECT DEVELOPED INABILITY TO SPEAK. HE WAS ADMITTED TO THE HOSPITAL AND DIAGNOSED WITH FRONTAL LOBE STROKE. SUBJECT WAS DISCHARGED 9/11/2020 WITH ONGOING SPEECH DEFICIT. HE WAS STARTED ON PLAVIX AND WILL BE STARTING SPEECH THERAPY. MEDICAL RECORDS WERE RECEIVED WHICH INCLUDED LAB RESULTS AND DIAGNOSTIC TEST RESULTS. RELEVANT OR ABNORMAL LAB TESTS INCLUDE: PTT 28.7 SEC, PT 13.4 SEC, INR 1.0, HGA1C 7.7%. FINDINGS FROM NONCONTRAST BRAIN CT SCAN ON 09/10/20 @ 1538 INLCUDE SMALL EVOLVING ACUTE INFARCTIONS IN THE LEFT INSULAR CORTEX AND ANTERIOR LEFT CORONA RADIATA, AND NO HEMORRHAGE. ULTRASOUND CAROTID DUPLEX BILATERAL COMPLETED ON 09/10/20 @ 1840 SHOWED NO STENOSIS BILATERALLY.' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 16:48:01
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	30 Oct 2020 16:45:45
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 16:45:45



**US3672278**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:25:56**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 16:45:45

**US3672278**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:25:56**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Oct 2020 16:45:45

**US3672278**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:25:56**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Oct 2020 16:46:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:25:56

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:06:34
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Query 'Please update con med page to reflect all of the conmeds listed in the source. Thanks! ' canceled (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 13:45:56
User opened query 'Please update con med page to reflect all of the conmeds listed in the source. Thanks! ' (Site from CRA).	(b) (4), (b) (6)	22 Sep 2020 12:57:15
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:55:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 18:30:24

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:25:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 18:39:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 18:39:51
Data point term sent to Coder	System	01 Sep 2020 18:39:14
User entered 'METOPROLOL'	(b) (4), (b) (6)	01 Sep 2020 18:38:11

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:38:11

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered 'MYOCARDIAL INFARCTION'	(b) (4), (b) (6)	01 Sep 2020 18:38:11

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered '25'	(b) (4), (b) (6)	01 Sep 2020 18:38:11



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:25:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Sep 2020 18:38:11

US3672278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:25:56**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:38:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:25:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered 'once daily (QD)'	(b) (4), (b) (6)	01 Sep 2020 18:38:11

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:25:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:38:11

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Sep 2020 18:38:11

US3672278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:25:56**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:38:11

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:25:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered 'UN UNK 1989'	(b) (4), (b) (6)	01 Sep 2020 18:38:11

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 18:38:11



**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 18:38:11

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:25:56**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:38:11

US3672278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:38:11

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:38:11

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 18:38:11

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Sep 2020 18:38:11

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:25:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 18:42:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 18:42:55
Data point term sent to Coder	System	01 Sep 2020 18:41:20
User entered 'LORATADINE'	(b) (4), (b) (6)	01 Sep 2020 18:40:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:25:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:40:19



US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:25:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered 'ALLERGIC RHINITIS'	(b) (4), (b) (6)	01 Sep 2020 18:40:19

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:25:56**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered '10'	(b) (4), (b) (6)	01 Sep 2020 18:40:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:25:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Sep 2020 18:40:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:25:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:40:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:25:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered 'as needed (PRN)'	(b) (4), (b) (6)	01 Sep 2020 18:40:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:25:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:40:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:25:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Sep 2020 18:40:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:25:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:40:19



US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:25:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered 'UN UNK 2000'	(b) (4), (b) (6)	01 Sep 2020 18:40:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:25:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 18:40:19

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:25:56**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 18:40:19

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:25:56**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 18:40:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:25:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:56:37
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 18:40:19

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:25:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 18:40:19

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:25:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 18:40:19

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:25:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 18:40:19



US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:25:56

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 12:36:34
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 12:36:34
	(b) (4)	
Data point term sent to Coder	System	22 Oct 2020 16:51:28
Coding entries removed.	(b) (4), (b) (6)	22 Oct 2020 16:50:47
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 06:13:54
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 06:13:54
	(b) (4)	
Data point term sent to Coder	System	28 Sep 2020 20:25:23
User entered 'benadryl'	(b) (4), (b) (6)	28 Sep 2020 20:24:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:25:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 20:24:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:25:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User closed query 'Per DM CLR: Please review if the specific affected location of leg cramps can be provided (e.g. Right, Left, bilateral ). Review and update Indication as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 18:39:39
Query 'Per DM CLR: Please review if the specific affected location of leg cramps can be provided (e.g. Right, Left, bilateral ). Review and update Indication as appropriate.' answered with 'location updated' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 16:51:03
User entered 'LEG CRAMPS (bilateral)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 16:50:47
User opened query 'Per DM CLR: Please review if the specific affected location of leg cramps can be provided (e.g. Right, Left, bilateral ). Review and update Indication as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 09:36:18
User entered 'leg cramps'	(b) (4), (b) (6)	28 Sep 2020 20:24:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:25:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered '25'	(b) (4), (b) (6)	28 Sep 2020 20:24:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:25:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Sep 2020 20:24:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:25:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:24:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:25:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'three times daily (TID)'	(b) (4), (b) (6)	28 Sep 2020 20:24:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:25:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:24:46



US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:25:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Sep 2020 20:24:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:25:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:24:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:25:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'un UNK 1990'	(b) (4), (b) (6)	28 Sep 2020 20:24:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:25:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 20:24:46

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:25:56**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 20:24:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:25:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:24:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:25:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 20:24:46

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:25:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	28 Sep 2020 20:24:46



US3672278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:25:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 20:24:46

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:25:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 20:24:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:25:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: SPIRONOLACTONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 05:10:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 05:10:48
Data point term sent to Coder	System	28 Sep 2020 20:26:26
User entered 'spironolactone'	(b) (4), (b) (6)	28 Sep 2020 20:25:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:25:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 20:25:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:25:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'myocardial infarction'	(b) (4), (b) (6)	28 Sep 2020 20:25:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:25:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered '12.5'	(b) (4), (b) (6)	28 Sep 2020 20:25:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:25:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Sep 2020 20:25:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:25:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:25:59



US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:25:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'once daily (QD)'	(b) (4), (b) (6)	28 Sep 2020 20:25:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:25:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:25:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:25:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Sep 2020 20:25:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:25:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:25:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:25:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'un UNK 2019'	(b) (4), (b) (6)	28 Sep 2020 20:25:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:25:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 20:25:59

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:25:56**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 20:25:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:25:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:25:59



US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:25:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 20:25:59

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:25:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 20:25:59

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:25:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 20:25:59

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:25:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 20:25:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:25:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIPIZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 20:28:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 20:28:39
Data point term sent to Coder	System	28 Sep 2020 20:27:27
User entered 'glipizide'	(b) (4), (b) (6)	28 Sep 2020 20:27:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:25:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 20:27:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:25:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'type II diabetes'	(b) (4), (b) (6)	28 Sep 2020 20:27:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:25:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered '10'	(b) (4), (b) (6)	28 Sep 2020 20:27:19



US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:25:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'mg (mg)'	(b) (4), (b) (6)	28 Sep 2020 20:27:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:25:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:27:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:25:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'once daily (QD)'	(b) (4), (b) (6)	28 Sep 2020 20:27:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:25:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:27:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:25:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	28 Sep 2020 20:27:19

US3672278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:25:56**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:27:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:25:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'un UNK 2014'	(b) (4), (b) (6)	28 Sep 2020 20:27:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:25:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered '0'	(b) (4), (b) (6)	28 Sep 2020 20:27:19



US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:25:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 20:27:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:25:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 20:27:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:25:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4), (b) (6)	28 Sep 2020 20:27:19

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:25:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 20:27:19

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:25:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 20:27:19

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:25:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Sep 2020 20:27:19

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:25:56

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:47
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Oct 2020 19:30:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	(b) (4)	23 Oct 2020 19:30:37
User closed query 'Drug name is LOSARTAN. Please update. Thanks' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 15:53:01
Data point term sent to Coder	System	19 Oct 2020 20:53:44
Query 'Drug name is LOSARTAN. Please update. Thanks' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	19 Oct 2020 20:53:18
User entered 'LOSARTAN' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Oct 2020 20:52:46
User opened query 'Drug name is LOSARTAN. Please update. Thanks' (Site from CRA).	(b) (4), (b) (6)	09 Oct 2020 13:52:28
User entered 'LASARTAN' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 18:19:00
Data point term sent to Coder	System	07 Oct 2020 18:13:39
User entered 'GLIPIZIDE'	(b) (4), (b) (6)	07 Oct 2020 18:13:24

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:25:56**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:47
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 18:13:24



US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:25:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:47
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'MYOCARDIAL INFARACTION'	(b) (4), (b) (6)	07 Oct 2020 18:19:00
reason for change: Data Entry Error		
User entered 'TYPE 2 DM'	(b) (4), (b) (6)	07 Oct 2020 18:13:24

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:25:56**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:47
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered '50' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 18:19:00
User entered '10'	(b) (4), (b) (6)	07 Oct 2020 18:13:24

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:25:56**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:47
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'mg (mg)'	(b) (4), (b) (6)	07 Oct 2020 18:13:24

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:25:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:47
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 18:13:24

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:25:56**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:47
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'once daily (QD)'	(b) (4), (b) (6)	07 Oct 2020 18:13:24

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:25:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:47
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 18:13:24

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:25:56**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:47
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Oct 2020 18:13:24

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:25:56**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:47
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 18:13:24



US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:25:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:47
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'UN UNK 1989' reason for change:	(b) (4), (b) (6)	07 Oct 2020 18:19:00
Data Entry Error		
User entered 'UN UNK 2019'	(b) (4), (b) (6)	07 Oct 2020 18:13:24

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:25:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:47
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 18:13:24

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:25:56**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:47
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 18:19:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 18:13:24

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:25:56**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:47
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered '10 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Oct 2020 18:19:00
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 18:13:24

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:25:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:47
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 18:13:24

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:25:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:47
User entered '1'	System	07 Oct 2020 18:13:24

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:25:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:47
User entered '1'	System	07 Oct 2020 18:13:24

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:25:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:47
User entered '804 (804)'	System	07 Oct 2020 18:13:24



US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:25:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 06:05:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Oct 2020 06:05:25
Data point term sent to Coder	System	07 Oct 2020 18:15:44
User entered 'LASIX'	(b) (4), (b) (6)	07 Oct 2020 18:14:48

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:25:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 18:14:48

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:25:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'MYCARDIAL INFARCTION'	(b) (4), (b) (6)	07 Oct 2020 18:14:48

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:25:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered '20'	(b) (4), (b) (6)	07 Oct 2020 18:14:48

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:25:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'mg (mg)'	(b) (4), (b) (6)	07 Oct 2020 18:14:48

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:25:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 18:14:48

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:25:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'once daily (QD)'	(b) (4), (b) (6)	07 Oct 2020 18:14:48

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:25:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 18:14:48



US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:25:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Oct 2020 18:14:48

US3672278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:25:56**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 18:14:48

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:25:56**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'UN UNK 1989'	(b) (4), (b) (6)	07 Oct 2020 18:14:48

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:25:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 18:14:48

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:25:56**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 18:14:48

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:25:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 18:14:48

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:25:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 18:14:48

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:25:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 18:14:48



**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:25:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 18:14:48

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:25:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Oct 2020 18:14:48

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:25:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
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)	07 Oct 2020 18:24:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 18:24:57
Data point term sent to Coder	System	07 Oct 2020 18:17:51
User entered 'METFORMIN'	(b) (4), (b) (6)	07 Oct 2020 18:16:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:25:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 18:16:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:25:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'TYPE 2 DM'	(b) (4), (b) (6)	07 Oct 2020 18:16:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:25:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered '500'	(b) (4), (b) (6)	07 Oct 2020 18:16:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:25:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'mg (mg)'	(b) (4), (b) (6)	07 Oct 2020 18:16:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:25:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 18:16:59



US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:25:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'once daily (QD)'	(b) (4), (b) (6)	07 Oct 2020 18:16:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:25:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 18:16:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:25:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Oct 2020 18:16:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:25:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 18:16:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:25:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'un UNK 2014'	(b) (4), (b) (6)	07 Oct 2020 18:16:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:25:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 18:16:59

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:25:56**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 18:16:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:25:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 18:16:59



US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:25:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 18:16:59

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:25:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 18:16:59

US3672278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:25:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 18:16:59

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:25:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Oct 2020 18:16:59

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:25:56

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL BISULFATE, PRODUCTSYNONYM: PLAVIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 18:24:59
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 18:24:59
	(b) (4)	
Data point term sent to Coder	System	07 Oct 2020 18:21:00
User entered 'PLAVIX'	(b) (4), (b) (6)	07 Oct 2020 18:20:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:25:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 18:20:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:25:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'FRONTAL LOBE STROKE'	(b) (4), (b) (6)	07 Oct 2020 18:20:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:25:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered '75'	(b) (4), (b) (6)	07 Oct 2020 18:20:52



US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:25:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'mg (mg)'	(b) (4), (b) (6)	07 Oct 2020 18:20:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:25:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 18:20:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:25:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'once daily (QD)'	(b) (4), (b) (6)	07 Oct 2020 18:20:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:25:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 18:20:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:25:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	07 Oct 2020 18:20:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:25:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 18:20:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:25:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered '11 Sep 2020'	(b) (4), (b) (6)	07 Oct 2020 18:20:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:25:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 18:20:52



**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:25:56**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 18:20:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:25:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 18:20:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:25:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 18:20:52

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:25:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 18:20:52

US3672278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:25:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Oct 2020 18:20:52

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:25:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Oct 2020 18:20:52

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:25:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:51
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Oct 2020 18:24:59
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Oct 2020 18:24:59
	(b) (4)	
Data point term sent to Coder	System	07 Oct 2020 18:23:03
User entered 'INFLUENZA VACCINE'	(b) (4), (b) (6)	07 Oct 2020 18:22:50

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:25:56**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:51
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 18:22:50



**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:25:56**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:51
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'INFLUENZA PROPHYLAXIS'	(b) (4), (b) (6)	07 Oct 2020 18:22:50

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:25:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:51
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'l'	(b) (4), (b) (6)	07 Oct 2020 18:22:50

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:25:56**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:51
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'Other (OTHER)'	(b) (4), (b) (6)	07 Oct 2020 18:22:50

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:25:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:51
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'INJECTION'	(b) (4), (b) (6)	07 Oct 2020 18:22:50

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:25:56**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:51
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'once daily (QD)'	(b) (4), (b) (6)	07 Oct 2020 18:22:50

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:25:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:51
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 18:22:50

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:25:56**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:51
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'Other (OTHER)'	(b) (4), (b) (6)	07 Oct 2020 18:22:50

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:25:56**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:51
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'IM'	(b) (4), (b) (6)	07 Oct 2020 18:22:50



**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:25:56**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:51
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '04 Oct 2020'	(b) (4), (b) (6)	04 Nov 2020 16:54:25
	(b) (4), (b) (6)	07 Oct 2020 18:22:50

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:25:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:51
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered '0'	(b) (4), (b) (6)	07 Oct 2020 18:22:50

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:25:56**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:51
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 18:22:50

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:25:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:51
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered '04 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 18:22:50

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:25:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:51
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:54:25
User entered 'No (N)'	(b) (4), (b) (6)	07 Oct 2020 18:22:50

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:25:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:51
User entered '1'	System	07 Oct 2020 18:22:50

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:25:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:51
User entered '1'	System	07 Oct 2020 18:22:50

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:25:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:51
User entered '804 (804)'	System	07 Oct 2020 18:22:50



US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:25:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 07:18:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Mar 2021 07:18:07
Data point term sent to Coder	System	05 Mar 2021 21:08:00
Coding entries removed.	(b) (4), (b) (6)	05 Mar 2021 21:07:29
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 17:58:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 17:58:33
Data point term sent to Coder	System	04 Nov 2020 17:42:46
User entered 'LOSARTAN'	(b) (4), (b) (6)	04 Nov 2020 17:42:09

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:25:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 17:42:09

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:25:56

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:58:53
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
User closed query 'Per CDM Re-Query: Please update Indication with Prevention/Prophylaxis term. Thank you' (Site from DM).	(b) (4)	08 Mar 2021 06:30:02
Query 'Per CDM Re-Query: Please update Indication with Prevention/Prophylaxis term. Thank you' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 21:07:36
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 21:07:29
User entered 'MYOCARDIAL INFARCTION (prevention)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Mar 2021 21:07:29
User opened query 'Per CDM Re-Query: Please update Indication with Prevention/Prophylaxis term. Thank you' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 17:06:10
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) (6)	05 Mar 2021 17:06:10
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 'prophylaxis' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 20:28:59
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 14:13:49
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'myocardial infarction'	(b) (4), (b) (6)	04 Nov 2020 17:42:09

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:25:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered '25'	(b) (4), (b) (6)	04 Nov 2020 17:42:09

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:25:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Nov 2020 17:42:09

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:25:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 17:42:09

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:25:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'once daily (QD)'	(b) (4), (b) (6)	04 Nov 2020 17:42:09

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:25:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 17:42:09



US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:25:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Nov 2020 17:42:09

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:25:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 17:42:09

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:25:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered '11 Sep 2020'	(b) (4), (b) (6)	04 Nov 2020 17:42:09

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:25:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 17:42:09

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:25:56**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 17:42:09

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:25:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 17:42:09

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:25:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 17:42:09

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:25:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 17:42:09



**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:25:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 17:42:09

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:25:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Nov 2020 17:42:09

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:25:56

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:54
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
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)	04 Nov 2020 19:43:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 19:43:36
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
Data point term sent to Coder	System	04 Nov 2020 17:44:50
User entered 'aspirin'	(b) (4), (b) (6)	04 Nov 2020 17:44:25

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:25:56**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:54
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 17:44:25

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:25:56**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:54
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'frontal lobe stroke'	(b) (4), (b) (6)	04 Nov 2020 17:44:25

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:25:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:54
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered '325'	(b) (4), (b) (6)	04 Nov 2020 17:44:25

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:25:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:54
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Nov 2020 17:44:25

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:25:56**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:54
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 17:44:25



**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:25:56**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:54
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'once (ONCE)'	(b) (4), (b) (6)	04 Nov 2020 17:44:25

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:25:56**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:54
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 17:44:25

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:25:56**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:54
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Nov 2020 17:44:25

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:25:56**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:54
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 17:44:25

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:25:56**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:54
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered '10 Sep 2020'	(b) (4), (b) (6)	04 Nov 2020 17:44:25

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:25:56**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:54
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 17:44:25

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:25:56**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:54
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 17:44:25

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:25:56**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:54
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered '10 Sep 2020'	(b) (4), (b) (6)	04 Nov 2020 17:44:25



**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:25:56**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:54
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 17:44:25

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:25:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:54
User entered empty.	System	04 Nov 2020 17:44:25

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:25:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:54
User entered empty.	System	04 Nov 2020 17:44:25

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:25:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:33:54
User entered empty.	System	04 Nov 2020 17:44:25

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:25:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Mar 2021 04:23:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Mar 2021 04:23:42
Data point term sent to Coder	System	19 Mar 2021 14:58:48
Coding entries removed.	(b) (4), (b) (6)	19 Mar 2021 14:58:16
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DIPHENHYDRAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 21:10:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 21:10:31
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DIPHENHYDRAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 20:55:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 20:55:11
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
Data point term sent to Coder	System	04 Nov 2020 17:45:51
User entered 'diphenhydramine'	(b) (4), (b) (6)	04 Nov 2020 17:45:13

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:25:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 17:45:13

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:25:56

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:58:53
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
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) (6)	22 Mar 2021 18:38:28
DataPoint Un-verified.	(b) (4), (b) (6)	19 Mar 2021 14:58:16
User entered 'obstructive SLEEP APNEA' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:58:16
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 'added' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 14:58:04
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 14:14:36
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'sleep apnea'	(b) (4), (b) (6)	04 Nov 2020 17:45:13

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:25:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered '50'	(b) (4), (b) (6)	04 Nov 2020 17:45:13



US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:25:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Nov 2020 17:45:13

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:25:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 17:45:13

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:25:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'as needed (PRN)'	(b) (4), (b) (6)	04 Nov 2020 17:45:13

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:25:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 17:45:13

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:25:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Nov 2020 17:45:13

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:25:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 17:45:13

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:25:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered '10 Sep 2020'	(b) (4), (b) (6)	04 Nov 2020 17:45:13

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:25:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 17:45:13



**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:25:56**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 17:45:13

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:25:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 17:45:13

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:25:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 17:45:13

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:25:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 17:45:13

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:25:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 17:45:13

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:25:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 17:45:13

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:25:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: PRAVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Nov 2020 04:57:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 04:57:43
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
Data point term sent to Coder	System	04 Nov 2020 17:46:52
User entered 'pravastatin'	(b) (4), (b) (6)	04 Nov 2020 17:45:53

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:25:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 17:45:53



US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:25:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 17:04:27
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'AE' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 20:37:41
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 14:16:48
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'frontal lobe stroke'	(b) (4), (b) (6)	04 Nov 2020 17:45:53

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:25:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered '80'	(b) (4), (b) (6)	04 Nov 2020 17:45:53

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:25:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Nov 2020 17:45:53

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:25:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 17:45:53

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:25:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'once daily (QD)'	(b) (4), (b) (6)	04 Nov 2020 17:45:53

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:25:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 17:45:53

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:25:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Nov 2020 17:45:53

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:25:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 17:45:53



US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:25:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'un Apr 2020'	(b) (4), (b) (6)	04 Nov 2020 17:45:53

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:25:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 17:45:53

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:25:56**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 17:45:53

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:25:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 17:45:53

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:25:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 17:45:53

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:25:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 17:45:53

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:25:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 17:45:53

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:25:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Nov 2020 17:45:53



US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:25:56

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
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)	04 Nov 2020 17:47:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 17:47:25
Data point term sent to Coder	System	04 Nov 2020 17:46:52
User entered 'metformin'	(b) (4), (b) (6)	04 Nov 2020 17:46:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:25:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 17:46:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:25:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
User closed query ""Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med 9. Review and reconcile start/stop dates so there is no overlapping. Update Con Med eCRF as appropriate. "" (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 18:40:41
Query ""Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med 9. Review and reconcile start/stop dates so there is no overlapping. Update Con Med eCRF as appropriate. "" answered with 'no overlap just unknown transition' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 14:59:12
User opened query ""Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med 9. Review and reconcile start/stop dates so there is no overlapping. Update Con Med eCRF as appropriate. "" (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 14:17:19
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'type 2 diabetes'	(b) (4), (b) (6)	04 Nov 2020 17:46:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:25:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered '500'	(b) (4), (b) (6)	04 Nov 2020 17:46:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:25:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Nov 2020 17:46:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:25:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 17:46:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:25:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'twice daily (BID)'	(b) (4), (b) (6)	04 Nov 2020 17:46:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:25:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 17:46:46



US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:25:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Nov 2020 17:46:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:25:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 17:46:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:25:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'un Oct 2020'	(b) (4), (b) (6)	04 Nov 2020 17:46:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:25:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 17:46:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:25:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 17:46:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:25:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 17:46:46

US3672278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:25:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	08 Apr 2021 21:43:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 18:54:30
User entered 'No (N)'	(b) (4), (b) (6)	04 Nov 2020 17:46:46

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:25:56**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	04 Nov 2020 17:46:46



**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:25:56**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 17:46:46

**US3672278**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:25:56**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Nov 2020 17:46:46

US3672278

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:25:56

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:06:34
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:58:58
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Yes (Y)'	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 17:32:38

**US3672278**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:59:08
User signature succeeded.	Cynthia Strout (b) (4)	14 Apr 2021 20:20:02
Signature has been broken.	(b) (4), (b) (6)	22 Mar 2021 13:35:05
User entered '10 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Mar 2021 13:35:05
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '11 Sep 2020'	Patty Howenstine (b) (4)	24 Feb 2021 17:40:31

US3672278

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:25:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:59:08
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'CT Head Stroke Protocol W/O Contrast'	Patty Howenstine (b) (4)	24 Feb 2021 17:40:31

US3672278

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:25:56

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:59:08
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Adverse Event (AE)'	Patty Howenstine (b) (4)	24 Feb 2021 17:40:31

US3672278

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:25:56

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:59:08
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered empty.	Patty Howenstine (b) (4)	24 Feb 2021 17:40:31

US3672278

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:25:56

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:35
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:59:08
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '10 Sep 2020'	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 17:40:59



US3672278

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:25:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:35
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:59:08
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'cAROTID DUPLEX'	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 17:40:59

US3672278

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:25:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:35
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:59:08
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'Adverse Event (AE)'	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 17:40:59

US3672278

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:25:56

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:35
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:59:08
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered empty.	(b) (4) Patty Howenstine (b) (4) (b) (4)	24 Feb 2021 17:40:59

US3672278

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:25:56

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:40
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:59:08
User signature succeeded.	Cynthia Strout (b) (4)	14 Apr 2021 20:20:02
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	14 Apr 2021 14:58:25
User entered '10 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 14:58:25
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Mar 2021 13:35:37
User entered 'un Sep 2020' (non-conformant).	(b) (4), (b) (6)	22 Mar 2021 13:35:37

US3672278

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:25:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:40
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:59:08
User signature succeeded.	Cynthia Strout (b) (4)	14 Apr 2021 20:20:02
User entered 'speech therapy'	(b) (4), (b) (6)	22 Mar 2021 13:35:37

US3672278

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:25:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:40
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:59:08
User signature succeeded.	Cynthia Strout (b) (4)	14 Apr 2021 20:20:02
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	22 Mar 2021 13:35:37

US3672278

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:25:56

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:40
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:59:08
User signature succeeded.	Cynthia Strout (b) (4)	14 Apr 2021 20:20:02
User entered empty.	(b) (4), (b) (6)	22 Mar 2021 13:35:37

US3672278

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:25:56

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:43
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:59:08
User signature succeeded.	Cynthia Strout (b) (4)	14 Apr 2021 20:20:02
User entered '10 Sep 2020'	(b) (4), (b) (6)	22 Mar 2021 13:36:07



US3672278

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:25:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:43
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:59:08
User signature succeeded.	Cynthia Strout (b) (4)	14 Apr 2021 20:20:02
User entered 'diagnostic lab testing'	(b) (4), (b) (6)	22 Mar 2021 13:36:07

US3672278

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:25:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:43
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:59:08
User signature succeeded.	Cynthia Strout (b) (4)	14 Apr 2021 20:20:02
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	22 Mar 2021 13:36:07

US3672278

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 09:25:56

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:10:43
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:59:08
User signature succeeded.	Cynthia Strout (b) (4)	14 Apr 2021 20:20:02
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Mar 2021 13:36:07

**US3672278**

**Folder: End of Study (1)**

**Form: Dosing Discontinuation**

**Generated On: 10 Jun 2021 09:25:56**

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:27:09
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:55:00
User entered '28 Sep 2020'	(b) (4), (b) (6)	27 Oct 2020 23:14:01

US3672278

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:25:56

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:27:09
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:55:00
User entered 'SAE (specify) (SAE)'	(b) (4), (b) (6)	27 Oct 2020 23:14:01

US3672278

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:25:56

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:27:09
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:59:13
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User closed query 'Per CDM: please record the record line number per CCGs (i.e. AE#1 or SAE#1, etc.) instead of AEID number' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 08:54:08
Query 'Per CDM: please record the record line number per CCGs (i.e. AE#1 or SAE#1, etc.) instead of AEID number' answered with 'Correction made.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 20:11:44
User entered 'AE#1' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 20:11:37
User opened query 'Per CDM: please record the record line number per CCGs (i.e. AE#1 or SAE#1, etc.) instead of AEID number' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 01:50:29
User closed query 'Per CDM: Please record SAE record number instead of details ' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 17:17:27
Query 'Per CDM: Please record SAE record number instead of details ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 21:17:24
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 21:17:19
User entered 'USA-US116-2020-MRNA-1273-P301000001' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 21:17:19
User opened query 'Per CDM: Please record SAE record number instead of details ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 16:37:39
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:55:00
User entered 'FRONTAL LOBE STROKE'	(b) (4), (b) (6)	27 Oct 2020 23:14:01

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered		
'USA-US116-2020-MRNA-1273-P301000001'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:19
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'Yes (Y)'	System	12 Sep 2020 19:18:32



**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:15
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'Yes (Y)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:21:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 17:16:15
Un-reviewed for Safety.	System	02 Nov 2020 17:15:34
DataPoint Un-verified.	System	02 Nov 2020 17:15:34
User entered 'Yes (Y)'	System	02 Nov 2020 17:15:34
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:04
Amendment Manager: User entered 'Cynthia'	System	14 Sep 2020 22:07:24

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:01
Amendment Manager: User entered 'Strout'	System	14 Sep 2020 22:07:24



**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:00
Amendment Manager: User entered '1156 Bowman Road'	System	14 Sep 2020 22:07:24

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:59
Amendment Manager: User entered 'Mount Pleasant' System		14 Sep 2020 22:07:24

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:56

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:57:09
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:01:34
Un-reviewed for Safety.	System	25 Nov 2020 14:47:26
DataPoint Un-verified.	System	25 Nov 2020 14:47:26
User entered empty.	System	25 Nov 2020 14:47:26
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 14:47:07
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:12
User entered 'South Carolina'	(b) (4), (b) (6)	16 Nov 2020 21:09:52

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:57
Amendment Manager: User entered '29464'	System	14 Sep 2020 22:07:24

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:56
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:42:35
User entered 'US' (non-conformant).	System	12 Sep 2020 19:21:23

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	25 Feb 2021 17:01:52
User entered '6'	System	25 Nov 2020 14:47:26
User entered '5'	System	12 Nov 2020 23:16:32
User entered '4'	System	02 Nov 2020 17:16:46
User entered '3'	System	28 Oct 2020 15:04:43
User entered '2'	System	23 Oct 2020 16:30:57
User entered '1'	System	12 Sep 2020 19:21:23

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered		
'USA-US116-2020-MRNA-1273-P301000001'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:19
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'Yes (Y)'	System	12 Sep 2020 19:18:32



**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:15
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'Yes (Y)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:21:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 17:16:15
Un-reviewed for Safety.	System	02 Nov 2020 17:15:34
DataPoint Un-verified.	System	02 Nov 2020 17:15:34
User entered 'Yes (Y)'	System	02 Nov 2020 17:15:34
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:04
Amendment Manager: User entered 'Cynthia'	System	14 Sep 2020 22:07:24

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:01
Amendment Manager: User entered 'Strout'	System	14 Sep 2020 22:07:24



**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:00
Amendment Manager: User entered '1156 Bowman Road'	System	14 Sep 2020 22:07:24

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:59
Amendment Manager: User entered 'Mount Pleasant' System		14 Sep 2020 22:07:24

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:56

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:57:09
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:01:34
Un-reviewed for Safety.	System	25 Nov 2020 14:47:26
DataPoint Un-verified.	System	25 Nov 2020 14:47:26
User entered empty.	System	25 Nov 2020 14:47:26
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 14:47:07
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:12
User entered 'South Carolina'	(b) (4), (b) (6)	16 Nov 2020 21:09:52

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:57
Amendment Manager: User entered '29464'	System	14 Sep 2020 22:07:24

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:56
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:42:35
User entered 'US' (non-conformant).	System	12 Sep 2020 19:21:23

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	25 Feb 2021 17:01:52
User entered '6'	System	25 Nov 2020 14:47:26
User entered '5'	System	12 Nov 2020 23:16:32
User entered '4'	System	02 Nov 2020 17:16:46
User entered '3'	System	28 Oct 2020 15:04:43
User entered '2'	System	23 Oct 2020 16:30:57
User entered '1'	System	12 Sep 2020 19:21:23

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:25:56**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 12:58:56
User entered '12/Sep/2020 15:21'	System	12 Sep 2020 19:21:23

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:25:56

**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 18:05:45
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:59
User entered 'I'	(b) (4), (b) (6)	12 Sep 2020 19:21:23



**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered		
'USA-US116-2020-MRNA-1273-P301000001'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:19
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'Yes (Y)'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:15
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'Yes (Y)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:21:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 17:16:15
Un-reviewed for Safety.	System	02 Nov 2020 17:15:34
DataPoint Un-verified.	System	02 Nov 2020 17:15:34
User entered 'Yes (Y)'	System	02 Nov 2020 17:15:34
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32



**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:04
Amendment Manager: User entered 'Cynthia'	System	14 Sep 2020 22:07:24

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:01
Amendment Manager: User entered 'Strout'	System	14 Sep 2020 22:07:24

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:00
Amendment Manager: User entered '1156 Bowman Road'	System	14 Sep 2020 22:07:24

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:59
Amendment Manager: User entered 'Mount Pleasant' System		14 Sep 2020 22:07:24

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:56

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:57:09
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:01:34
Un-reviewed for Safety.	System	25 Nov 2020 14:47:26
DataPoint Un-verified.	System	25 Nov 2020 14:47:26
User entered empty.	System	25 Nov 2020 14:47:26
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 14:47:07
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:12
User entered 'South Carolina'	(b) (4), (b) (6)	16 Nov 2020 21:09:52

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:57
Amendment Manager: User entered '29464'	System	14 Sep 2020 22:07:24

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:56
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:42:35
User entered 'US' (non-conformant).	System	12 Sep 2020 19:21:23

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	25 Feb 2021 17:01:52
User entered '6'	System	25 Nov 2020 14:47:26
User entered '5'	System	12 Nov 2020 23:16:32
User entered '4'	System	02 Nov 2020 17:16:46
User entered '3'	System	28 Oct 2020 15:04:43
User entered '2'	System	23 Oct 2020 16:30:57
User entered '1'	System	12 Sep 2020 19:21:23



**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:25:56**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:21:57
User entered '23/Oct/2020 16:30'	System	23 Oct 2020 16:30:57

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:25:56

**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 18:05:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:21:58
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 16:33:21
User entered 'I'	(b) (4), (b) (6)	23 Oct 2020 16:30:57

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered		
'USA-US116-2020-MRNA-1273-P301000001'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:19
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'Yes (Y)'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 12:58:15
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'Yes (Y)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:21:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 17:16:15
Un-reviewed for Safety.	System	02 Nov 2020 17:15:34
DataPoint Un-verified.	System	02 Nov 2020 17:15:34
User entered 'Yes (Y)'	System	02 Nov 2020 17:15:34
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32



**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:04
Amendment Manager: User entered 'Cynthia'	System	14 Sep 2020 22:07:24

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:01
Amendment Manager: User entered 'Strout'	System	14 Sep 2020 22:07:24

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:00
Amendment Manager: User entered '1156 Bowman Road'	System	14 Sep 2020 22:07:24

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:59
Amendment Manager: User entered 'Mount Pleasant' System		14 Sep 2020 22:07:24

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:56

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:57:09
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:01:34
Un-reviewed for Safety.	System	25 Nov 2020 14:47:26
DataPoint Un-verified.	System	25 Nov 2020 14:47:26
User entered empty.	System	25 Nov 2020 14:47:26
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 14:47:07
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:12
User entered 'South Carolina'	(b) (4), (b) (6)	16 Nov 2020 21:09:52

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:57
Amendment Manager: User entered '29464'	System	14 Sep 2020 22:07:24



US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:56

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:56
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:42:35
User entered 'US' (non-conformant).	System	12 Sep 2020 19:21:23

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	25 Feb 2021 17:01:52
User entered '6'	System	25 Nov 2020 14:47:26
User entered '5'	System	12 Nov 2020 23:16:32
User entered '4'	System	02 Nov 2020 17:16:46
User entered '3'	System	28 Oct 2020 15:04:43
User entered '2'	System	23 Oct 2020 16:30:57
User entered '1'	System	12 Sep 2020 19:21:23

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 09:25:56**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:22:15
User entered '28/Oct/2020 15:04'	System	28 Oct 2020 15:04:43

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:25:56

**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 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:22:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 17:16:15
User entered 'I'	(b) (4), (b) (6)	28 Oct 2020 15:04:43

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered		
'USA-US116-2020-MRNA-1273-P301000001'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:19
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'Yes (Y)'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:15
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32



**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'Yes (Y)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:21:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 17:16:15
Un-reviewed for Safety.	System	02 Nov 2020 17:15:34
DataPoint Un-verified.	System	02 Nov 2020 17:15:34
User entered 'Yes (Y)'	System	02 Nov 2020 17:15:34
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:04
Amendment Manager: User entered 'Cynthia'	System	14 Sep 2020 22:07:24

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:01
Amendment Manager: User entered 'Strout'	System	14 Sep 2020 22:07:24

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:00
Amendment Manager: User entered '1156 Bowman Road'	System	14 Sep 2020 22:07:24

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:59
Amendment Manager: User entered 'Mount Pleasant' System		14 Sep 2020 22:07:24



US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:56

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:57:09
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:01:34
Un-reviewed for Safety.	System	25 Nov 2020 14:47:26
DataPoint Un-verified.	System	25 Nov 2020 14:47:26
User entered empty.	System	25 Nov 2020 14:47:26
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 14:47:07
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:12
User entered 'South Carolina'	(b) (4), (b) (6)	16 Nov 2020 21:09:52

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:57
Amendment Manager: User entered '29464'	System	14 Sep 2020 22:07:24

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:56
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:42:35
User entered 'US' (non-conformant).	System	12 Sep 2020 19:21:23

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	25 Feb 2021 17:01:52
User entered '6'	System	25 Nov 2020 14:47:26
User entered '5'	System	12 Nov 2020 23:16:32
User entered '4'	System	02 Nov 2020 17:16:46
User entered '3'	System	28 Oct 2020 15:04:43
User entered '2'	System	23 Oct 2020 16:30:57
User entered '1'	System	12 Sep 2020 19:21:23

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 09:25:56**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:22:23
User entered '02/Nov/2020 17:16'	System	02 Nov 2020 17:16:46

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:25:56

**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 18:05:45
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Nov 2020 14:47:07
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 16:22:24
User entered 'I'	(b) (4), (b) (6)	02 Nov 2020 17:16:46

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered		
'USA-US116-2020-MRNA-1273-P301000001'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:19
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'Yes (Y)'	System	12 Sep 2020 19:18:32



**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:15
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'Yes (Y)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:21:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 17:16:15
Un-reviewed for Safety.	System	02 Nov 2020 17:15:34
DataPoint Un-verified.	System	02 Nov 2020 17:15:34
User entered 'Yes (Y)'	System	02 Nov 2020 17:15:34
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:04
Amendment Manager: User entered 'Cynthia'	System	14 Sep 2020 22:07:24

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:01
Amendment Manager: User entered 'Strout'	System	14 Sep 2020 22:07:24



**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:00
Amendment Manager: User entered '1156 Bowman Road'	System	14 Sep 2020 22:07:24

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:59
Amendment Manager: User entered 'Mount Pleasant' System		14 Sep 2020 22:07:24

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:56

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:57:09
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:01:34
Un-reviewed for Safety.	System	25 Nov 2020 14:47:26
DataPoint Un-verified.	System	25 Nov 2020 14:47:26
User entered empty.	System	25 Nov 2020 14:47:26
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 14:47:07
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:12
User entered 'South Carolina'	(b) (4), (b) (6)	16 Nov 2020 21:09:52

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:57
Amendment Manager: User entered '29464'	System	14 Sep 2020 22:07:24

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:56

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:56
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:42:35
User entered 'US' (non-conformant).	System	12 Sep 2020 19:21:23

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	25 Feb 2021 17:01:52
User entered '6'	System	25 Nov 2020 14:47:26
User entered '5'	System	12 Nov 2020 23:16:32
User entered '4'	System	02 Nov 2020 17:16:46
User entered '3'	System	28 Oct 2020 15:04:43
User entered '2'	System	23 Oct 2020 16:30:57
User entered '1'	System	12 Sep 2020 19:21:23

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (5)**

**Generated On: 10 Jun 2021 09:25:56**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 16:16:59
User entered '12/Nov/2020 18:16'	System	12 Nov 2020 23:16:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:25:56

**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 18:05:45
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Nov 2020 14:47:07
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:17:16
User entered 'I'	(b) (4), (b) (6)	12 Nov 2020 23:16:32



**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered		
'USA-US116-2020-MRNA-1273-P301000001'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:19
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'Yes (Y)'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:15
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'Yes (Y)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:21:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 17:16:15
Un-reviewed for Safety.	System	02 Nov 2020 17:15:34
DataPoint Un-verified.	System	02 Nov 2020 17:15:34
User entered 'Yes (Y)'	System	02 Nov 2020 17:15:34
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32



US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:04
Amendment Manager: User entered 'Cynthia'	System	14 Sep 2020 22:07:24

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:01
Amendment Manager: User entered 'Strout'	System	14 Sep 2020 22:07:24

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:00
Amendment Manager: User entered '1156 Bowman Road'	System	14 Sep 2020 22:07:24

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:59
Amendment Manager: User entered 'Mount Pleasant' System		14 Sep 2020 22:07:24

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:56

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:57:09
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:01:34
Un-reviewed for Safety.	System	25 Nov 2020 14:47:26
DataPoint Un-verified.	System	25 Nov 2020 14:47:26
User entered empty.	System	25 Nov 2020 14:47:26
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 14:47:07
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:12
User entered 'South Carolina'	(b) (4), (b) (6)	16 Nov 2020 21:09:52

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:57
Amendment Manager: User entered '29464'	System	14 Sep 2020 22:07:24

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:56

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:56
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:42:35
User entered 'US' (non-conformant).	System	12 Sep 2020 19:21:23

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	25 Feb 2021 17:01:52
User entered '6'	System	25 Nov 2020 14:47:26
User entered '5'	System	12 Nov 2020 23:16:32
User entered '4'	System	02 Nov 2020 17:16:46
User entered '3'	System	28 Oct 2020 15:04:43
User entered '2'	System	23 Oct 2020 16:30:57
User entered '1'	System	12 Sep 2020 19:21:23



**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (6)**

**Generated On: 10 Jun 2021 09:25:56**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:57:09
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '25/Nov/2020 14:47'	(b) (4) System	25 Nov 2020 14:47:26

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:25:56

**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)	20 Apr 2021 14:57:09
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:01:34
User entered 'I'	(b) (4), (b) (6)	25 Nov 2020 14:47:26

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:20
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered		
'USA-US116-2020-MRNA-1273-P301000001'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:19
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'Yes (Y)'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:17
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:15
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'Yes (Y)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 16:21:44
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 17:16:15
Un-reviewed for Safety.	System	02 Nov 2020 17:15:34
DataPoint Un-verified.	System	02 Nov 2020 17:15:34
User entered 'Yes (Y)'	System	02 Nov 2020 17:15:34
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:23
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32



**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:07
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Sep 2020 12:58:13
Reviewed for Safety.	(b) (4), (b) (6)	12 Sep 2020 19:21:17
User entered 'No (N)'	System	12 Sep 2020 19:18:32

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:04
Amendment Manager: User entered 'Cynthia'	System	14 Sep 2020 22:07:24

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:01
Amendment Manager: User entered 'Strout'	System	14 Sep 2020 22:07:24

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:58:00
Amendment Manager: User entered '1156 Bowman Road'	System	14 Sep 2020 22:07:24

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:59
Amendment Manager: User entered 'Mount Pleasant' System		14 Sep 2020 22:07:24

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 10 Jun 2021 09:25:56

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:57:09
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 17:01:34
Un-reviewed for Safety.	System	25 Nov 2020 14:47:26
DataPoint Un-verified.	System	25 Nov 2020 14:47:26
User entered empty.	System	25 Nov 2020 14:47:26
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 14:47:07
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:33:12
User entered 'South Carolina'	(b) (4), (b) (6)	16 Nov 2020 21:09:52

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:57
Amendment Manager: User entered '29464'	System	14 Sep 2020 22:07:24



**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:30:46
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 12:57:56
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 02:42:35
User entered 'US' (non-conformant).	System	12 Sep 2020 19:21:23

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:25:56**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	25 Feb 2021 17:01:52
User entered '6'	System	25 Nov 2020 14:47:26
User entered '5'	System	12 Nov 2020 23:16:32
User entered '4'	System	02 Nov 2020 17:16:46
User entered '3'	System	28 Oct 2020 15:04:43
User entered '2'	System	23 Oct 2020 16:30:57
User entered '1'	System	12 Sep 2020 19:21:23

**US3672278**

**Folder: SAE USA-US116-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (7)**

**Generated On: 10 Jun 2021 09:25:56**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:57:09
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered '25/Feb/2021 12:01'	(b) (4) System	25 Feb 2021 17:01:52

US3672278

Folder: SAE USA-US116-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:25:56

**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)	20 Apr 2021 14:57:09
User signature succeeded.	Cynthia Strout (b) (4)	05 Mar 2021 18:05:45
User entered 'I'	(b) (4), (b) (6)	25 Feb 2021 17:01:52