

US3822278 (Prod: Tryon Medical Partners, PLLC)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:56:47

All time stamps listed in this document are displayed in GMT

US3822278

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 21:58:01

Generated On: 10 Jun 2021 09:56:47

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[Participant ID](#)

US3822278

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

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US3822278

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 20:51:29

Generated On: 10 Jun 2021 09:56:47

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 14 Feb 2021 20:51:29

Generated On: 10 Jun 2021 09:56:47

Date of Birth (MMM yyyy)	(b) (6) 1951
Age	69
Age Units	YEARS
Age (Derived)	69
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 14 Feb 2021 20:51:29

Generated On: 10 Jun 2021 09:56:47

Date of Informed Consent ( <i>dd MMM yyyy</i> )	26 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 14 Feb 2021 20:51:29

Generated On: 10 Jun 2021 09:56:47

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 14 Feb 2021 20:51:29

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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) 14 Feb 2021 20:51:29

Generated On: 10 Jun 2021 09:56:47

Condition	DIABETES
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: Medical History (2)

Data signed: (b) (4) 14 Feb 2021 20:51:29

Generated On: 10 Jun 2021 09:56:47

Condition	SEASONAL ALLERGIES
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: Medical History (3)

Data signed: (b) (4) 14 Feb 2021 20:51:29

Generated On: 10 Jun 2021 09:56:47

Condition	HYPERTENSION
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: Medical History (4)

Data signed: (b) (4) 14 Feb 2021 20:51:29

Generated On: 10 Jun 2021 09:56:47

Condition	ATHEROSCLEROSIS
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: Medical History (5)

Data signed: (b) (4) 14 Feb 2021 20:51:29

Generated On: 10 Jun 2021 09:56:47

Condition	ACID REFLUX
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: Medical History (6)

Data signed: (b) (4) 14 Feb 2021 20:51:29

Generated On: 10 Jun 2021 09:56:47

Condition	ASTHMA
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: Medical History (7)

Data signed: (b) (4) 14 Feb 2021 20:51:29

Generated On: 10 Jun 2021 09:56:47

Condition	HIGH TRIGLYCERIDES
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: Medical History (8)

Data signed: (b) (4) 14 Feb 2021 20:51:29

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Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN JAN 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 14 Feb 2021 20:51:29

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Condition	HYPOTHYROIDISM
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) 14 Feb 2021 20:51:29

Generated On: 10 Jun 2021 09:56:47

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	26 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	14:40 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 14:40
Height ( <i>xxx.x</i> )	63 in
Weight ( <i>xxx.x</i> )	150 lb
BMI ( <i>xxx.x</i> )	26.62687 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 14 Feb 2021 20:51:29

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 14 Feb 2021 20:51:29

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Date of assessment (dd MMM yyyy) 26 AUG 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

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

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN JAN 2005

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 14 Feb 2021 20:51:29

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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**

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

**No Risk Identified** True

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 14 Feb 2021 20:51:29

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 20:51:29

Generated On: 10 Jun 2021 09:56:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 14 Feb 2021 20:51:29

Generated On: 10 Jun 2021 09:56:47

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

What was the participant's randomization number? 188253

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) 14 Feb 2021 20:51:29

Generated On: 10 Jun 2021 09:56:47

Height	
Weight	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 14 Feb 2021 20:51:29

Generated On: 10 Jun 2021 09:56:47

Height	
Weight	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 AUG 2020
Time of assessment (00:00-23:59)	14:40 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 14:40
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 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)	68 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 14 Feb 2021 20:51:29

Generated On: 10 Jun 2021 09:56:47

Height	
Weight	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 AUG 2020
Time of assessment (00:00-23:59)	15:45 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 15:45
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 14 Feb 2021 20:51:29

Generated On: 10 Jun 2021 09:56:47

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 14 Feb 2021 20:51:29

Generated On: 10 Jun 2021 09:56:47

Was study treatment given? Yes ☒  
No ☐

If No, reason not given

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

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

Treatment Date and Time (derived) 26 AUG 2020 15:15

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Feb 2021 20:51:29

Generated On: 10 Jun 2021 09:56:47

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 AUG 2020
Collection time (00:00-23:59)	14:50 (24 HR)
Collection date and time (derived)	26 AUG 2020 14:50

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 14 Feb 2021 20:51:29

Generated On: 10 Jun 2021 09:56:47

Collection date (dd MMM yyyy)			26 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:07	26 AUG 2020 12:07
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 20:51:29

Generated On: 10 Jun 2021 09:56:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 15:36

PC Open Date & Time

26 AUG 2020 15:35

PC Close Date & Time

26 AUG 2020 18:05



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.8 °F

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

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

PC Time Stamp	27 AUG 2020 00:49
PC Open Date & Time	26 AUG 2020 19:00
PC Close Date & Time	27 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

27 AUG 2020 19:05

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

28 AUG 2020 21:50

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:56:47

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.0 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

30 AUG 2020 00:06

---

PC Open Date & Time

29 AUG 2020 12:00

---

PC Close Date & Time

30 AUG 2020 11:59

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US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:56:47

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

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

30 AUG 2020 16:16

---

PC Open Date & Time

30 AUG 2020 12:00

---

PC Close Date & Time

31 AUG 2020 11:59

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US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:56:47

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**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

96.7 °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 19:11

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

**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 ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 15:37

PC Open Date & Time

26 AUG 2020 15:35

PC Close Date & Time

26 AUG 2020 18:05



US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 00:49

PC Open Date & Time

26 AUG 2020 19:00

PC Close Date & Time

27 AUG 2020 11:59

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☒

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 19:08

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 21:51

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 00:07

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 16:16

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 19:11

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐



US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 15:39
PC Open Date & Time	26 AUG 2020 15:35
PC Close Date & Time	26 AUG 2020 18:05

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 00:50
PC Open Date & Time	26 AUG 2020 19:00
PC Close Date & Time	27 AUG 2020 11:59

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:47

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 19:08
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:47

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:47

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 21:51
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:47

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 00:08
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:47

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 16:17
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:47

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:47

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

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

**DAY 7**

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:47

Yes ☐

PC Time stamp

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3822278

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 20:51:29

Generated On: 10 Jun 2021 09:56:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3822278

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 20:51:19

Generated On: 10 Jun 2021 09:56:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822278

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 20:51:18

Generated On: 10 Jun 2021 09:56:47

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*

US3822278

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 20:51:18

Generated On: 10 Jun 2021 09:56:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822278

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 20:51:18

Generated On: 10 Jun 2021 09:56:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3822278

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 20:51:18

Generated On: 10 Jun 2021 09:56:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822278

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 20:51:29

Generated On: 10 Jun 2021 09:56:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 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

US3822278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 14 Feb 2021 20:51:29

Generated On: 10 Jun 2021 09:56:47

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 SEP 2020
Time of assessment (00:00-23:59)	14:06 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 14:06
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)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3822278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 14 Feb 2021 20:51:29

Generated On: 10 Jun 2021 09:56:47

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 SEP 2020
Time of assessment (00:00-23:59)	15:39 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 15:39
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG



US3822278

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 14 Feb 2021 20:51:29

Generated On: 10 Jun 2021 09:56:47

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3822278

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 14 Feb 2021 20:51:29

Generated On: 10 Jun 2021 09:56:47

Was study treatment given? Yes ☒  
No ☐

If No, reason not given

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 25 SEP 2020

What was the treatment time? (00:00-23:59) 15:08 (24 HR)

Treatment Date and Time (derived) 25 SEP 2020 15:08

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

US3822278

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Feb 2021 20:51:29

Generated On: 10 Jun 2021 09:56:47

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 SEP 2020

Collection time (00:00-23:59)

14:30 (24 HR)

Collection date and time (derived)

25 SEP 2020 14:30

US3822278

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 14 Feb 2021 20:51:29

Generated On: 10 Jun 2021 09:56:47

Collection date (dd MMM yyyy)			25 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:01	25 SEP 2020 15:01
Nasopharyngeal Swab 2	No		

US3822278

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 20:51:29

Generated On: 10 Jun 2021 09:56:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 15:41

PC Open Date & Time

25 SEP 2020 15:28

PC Close Date & Time

25 SEP 2020 17:58

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.8 °F

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

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

PC Time Stamp	25 SEP 2020 21:41
PC Open Date & Time	25 SEP 2020 18:53
PC Close Date & Time	26 SEP 2020 11:59

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59



US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.4 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

27 SEP 2020 12:33

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

29 SEP 2020 00:59

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.3 °F

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

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

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

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

PC Time Stamp 29 SEP 2020 20:09

PC Open Date & Time 29 SEP 2020 12:00

PC Close Date & Time 30 SEP 2020 11:59

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 6

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

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

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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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 00:14

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

**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 ☒

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

25 SEP 2020 15:42

PC Open Date & Time

25 SEP 2020 15:28

PC Close Date & Time

25 SEP 2020 17:58

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 21:43

PC Open Date & Time

25 SEP 2020 18:53

PC Close Date & Time

26 SEP 2020 11:59

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59



US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

30

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 12:37

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 00:59

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 20:09

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 00:14

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

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

No ☒

Yes ☐

PC Time stamp	25 SEP 2020 15:42
PC Open Date & Time	25 SEP 2020 15:28
PC Close Date & Time	25 SEP 2020 17:58

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

- None ☐
- No interference with activity ☒
- Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☐
- Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

- None ☒
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

- None ☒
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

- None ☒
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

- None ☒
- No interference with activity or  
1-2 episodes/24 hours ☐
- Some interference with activity  
or >2 episodes/24 hours ☐
- Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

- None ☒
- No interference with activity ☐
- Some interference with activity  
not requiring medical attention ☐
- Prevents daily activity and  
requires medical attention ☐



US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

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

No ☒

Yes ☐

PC Time stamp	25 SEP 2020 21:44
PC Open Date & Time	25 SEP 2020 18:53
PC Close Date & Time	26 SEP 2020 11:59

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:47

Yes ☐

PC Time stamp

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:47

		Yes <input type="checkbox"/>
PC Time stamp	27 SEP 2020 13:30	
PC Open Date & Time	27 SEP 2020 12:00	
PC Close Date & Time	28 SEP 2020 11:59	

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:47

		Yes <input type="checkbox"/>
PC Time stamp	29 SEP 2020 01:00	
PC Open Date & Time	28 SEP 2020 12:00	
PC Close Date & Time	29 SEP 2020 11:59	

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:47

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒



US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:47

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 20:10
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 6

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:47

Yes ☐

PC Time stamp

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:47

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

US3822278

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 20:51:19

Generated On: 10 Jun 2021 09:56:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3822278

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 20:51:19

Generated On: 10 Jun 2021 09:56:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822278

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 20:51:19

Generated On: 10 Jun 2021 09:56:47

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 9 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*



US3822278

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 20:51:19

Generated On: 10 Jun 2021 09:56:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822278

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 20:51:19

Generated On: 10 Jun 2021 09:56:47

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

NOTHING IS ENTERED IN CRIO

*If Contact Not Made, please provide Comments*

US3822278

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 20:51:19

Generated On: 10 Jun 2021 09:56:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822278

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 20:51:29

Generated On: 10 Jun 2021 09:56:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 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

US3822278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 14 Feb 2021 20:51:29

Generated On: 10 Jun 2021 09:56:47

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 OCT 2020
Time of assessment (00:00-23:59)	15:15 (24 HR)
Vital Signs Date and Time (derived)	27 OCT 2020 15:15
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)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3822278

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 14 Feb 2021 20:51:29

Generated On: 10 Jun 2021 09:56:47

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3822278

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Feb 2021 20:51:29

Generated On: 10 Jun 2021 09:56:47

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

27 OCT 2020

Collection time (00:00-23:59)

15:25 (24 HR)

Collection date and time (derived)

27 OCT 2020 15:25

US3822278

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 20:51:29

Generated On: 10 Jun 2021 09:56:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

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

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

Date and time of submission

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 NOV 2020 15:13:56

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

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

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

Date and time of submission

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

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

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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20 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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24 NOV 2020 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 96

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 NOV 2020 16:34:23

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59



US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	07 DEC 2020 09:46:09
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	15 DEC 2020 22:20:29
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 DEC 2020 20:28:17

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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

25 DEC 2020 01:45:26

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 JAN 2021 13:33:10

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 JAN 2021 17:38:35

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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15 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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19 JAN 2021 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 JAN 2021 22:48:13

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 JAN 2021 15:25:17

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 166

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

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	05 FEB 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 FEB 2021 23:59

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 FEB 2021 22:14:53

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	19 FEB 2021 14:41:51
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	26 FEB 2021 05:13:08
Patient Cloud Open Date & Time	26 FEB 2021 00:01
Patient Cloud Close Date & Time	02 MAR 2021 23:59

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 MAR 2021 13:12:16

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59



US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 MAR 2021 22:12:40

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 MAR 2021 13:17:13

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 MAR 2021 20:58:31

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 21:00:19

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 APR 2021 13:28:06

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2021 23:59

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 APR 2021 15:10:06

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59



US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAY 2021 18:06:47

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

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

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 271

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

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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21 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAY 2021 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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28 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUN 2021 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 285

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

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 292

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

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 299

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

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 306

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

No ☐

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐



**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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25 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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29 JUN 2021 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 313

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

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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02 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 JUL 2021 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

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

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 327

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

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 334

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

Have you been exposed to someone with known SARS-CoV-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 ☐



**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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23 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 JUL 2021 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

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

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 362

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

Have you been exposed to someone with known SARS-CoV-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 ☐



**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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20 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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24 AUG 2021 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 AUG 2021 23:59

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 376

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

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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03 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 SEP 2021 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 383

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

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 390

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

Have you been exposed to someone with known SARS-CoV-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 ☐



**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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17 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 SEP 2021 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 404

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

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

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

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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08 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 OCT 2021 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 418

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

Have you been exposed to someone with known SARS-CoV-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 ☐



**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 425

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

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 432

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

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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29 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 NOV 2021 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

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

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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05 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 NOV 2021 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

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



**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	12 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	16 NOV 2021 23:59
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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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19 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 NOV 2021 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

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

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 467

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

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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03 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 DEC 2021 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 474

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

Have you been exposed to someone with known SARS-CoV-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 ☐



**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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10 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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14 DEC 2021 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

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

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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31 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 JAN 2022 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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07 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 JAN 2022 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

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 ☐

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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14 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 JAN 2022 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

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

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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21 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 JAN 2022 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 523

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

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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28 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 FEB 2022 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

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



**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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04 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 FEB 2022 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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11 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 FEB 2022 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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18 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 FEB 2022 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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25 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 MAR 2022 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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04 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 MAR 2022 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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11 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 MAR 2022 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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18 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 MAR 2022 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 579

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

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>



**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 593

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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08 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 APR 2022 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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15 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 APR 2022 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 607

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

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

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

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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06 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAY 2022 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 628

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

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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13 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAY 2022 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 635

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

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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20 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAY 2022 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

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



**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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27 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAY 2022 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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10 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 JUN 2022 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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17 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 JUN 2022 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

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



**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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24 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 JUN 2022 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

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

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

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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01 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 JUL 2022 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 684

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

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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08 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 JUL 2022 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 698

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

Have you been exposed to someone with known SARS-CoV-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 ☐



**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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22 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 JUL 2022 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

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

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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05 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 AUG 2022 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	12 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	16 AUG 2022 23:59
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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 726

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

Fever (Temperature  $\geq$  100.4°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 ☐



**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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19 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 AUG 2022 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

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

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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26 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 AUG 2022 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

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

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 754

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

Have you been exposed to someone with known SARS-CoV-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 ☐



**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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16 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 SEP 2022 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

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

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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23 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 SEP 2022 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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30 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 OCT 2022 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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07 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 OCT 2022 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 782

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐



**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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14 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 OCT 2022 23:59

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US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

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 ☐

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 OCT 2022 23:59

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

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

**US3822278**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

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

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[Patient Cloud Open Date & Time](#)

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28 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 NOV 2022 23:59

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US3822278

**Folder: Cosmetic Injections and Dermal Fillers**

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

**Generated On: 10 Jun 2021 09:56:47**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		08 MAR 2021 13:12:44

US3822278

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:21:17

Generated On: 10 Jun 2021 09:56:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3822278

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:21:17

Generated On: 10 Jun 2021 09:56:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3822278

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:58:03

Generated On: 10 Jun 2021 09:56:47

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 21 DEC 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3822278

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:58:03

Generated On: 10 Jun 2021 09:56:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822278

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:58:03

Generated On: 10 Jun 2021 09:56:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3822278

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:58:03

Generated On: 10 Jun 2021 09:56:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822278

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 21:58:03

Generated On: 10 Jun 2021 09:56:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3822278

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 21:58:03

Generated On: 10 Jun 2021 09:56:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822278

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

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

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

Folder OID	VISIT4
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US3822278

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

Were vital signs assessed? Yes ☐  
No ☒

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

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

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

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

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

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

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

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

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

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

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

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

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

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

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

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



US3822278

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3822278

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 MAR 2021
Collection time (00:00-23:59)	14:27 (24 HR)
Collection date and time (derived)	19 MAR 2021 14:27

US3822278

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822278

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 06:23:00

Generated On: 10 Jun 2021 09:56:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3822278

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 06:23:00

Generated On: 10 Jun 2021 09:56:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822278

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

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*

**US3822278**

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

**Form: Continuing**

**Generated On: 10 Jun 2021 09:56:47**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3822278

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:56:47

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



**US3822278**

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

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

**Generated On: 10 Jun 2021 09:56:47**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3822278

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 21:58:02

Generated On: 10 Jun 2021 09:56:47

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

Visit date (dd MMM yyyy)	13 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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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 23 Apr 2021 14:44:35

Generated On: 10 Jun 2021 09:56:47

Date of updated informed consent (dd MMM yyyy) 13 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 12 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

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

US3822278

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 21:58:02

Generated On: 10 Jun 2021 09:56:47

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 JAN 2021
Collection time (00:00-23:59)	15:58 (24 HR)
Collection date and time (derived)	13 JAN 2021 15:58

US3822278

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 21:58:02

Generated On: 10 Jun 2021 09:56:47

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 JAN 2021
Collection time (00:00 - 23:59)	16:09
Collection Date and Time (derived)	13 JAN 2021 16:09

US3822278

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 18:59:32

Generated On: 10 Jun 2021 09:56:47

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3822278

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 02 Apr 2021 21:58:01

Generated On: 10 Jun 2021 09:56:47

AEID	USA-US126-2020-MRNA-1273-P30 1000003
Adverse event	DEHYDRATION
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)	26 SEP 2020
Start time (00:00-23:59)	15:00 (24 HR)
AE start date and time (derived)	26 SEP 2020 15:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	28 SEP 2020
End time (00:00-23:59)	00:00 (24 HR)
AE End Date and Time (derived)	28 SEP 2020 00:00
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)	26 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	28 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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US3822278

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 02 Apr 2021 21:58:01

Generated On: 10 Jun 2021 09:56:47

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PATIENT HAD BAD GAIT AND FELL AFTER A LUMBAR PUNCTURE.
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) 02 Apr 2021 21:58:01

Generated On: 10 Jun 2021 09:56:47

AEID	USA-US126-2020-MRNA-1273-P30 1000009
Adverse event	FATIGUE
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)	26 SEP 2020
Start time (00:00-23:59)	15:00 (24 HR)
AE start date and time (derived)	26 SEP 2020 15:00
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	28 SEP 2020
End time (00:00-23:59)	00:00 (24 HR)
AE End Date and Time (derived)	28 SEP 2020 00:00
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 02 Apr 2021 21:58:01

Generated On: 10 Jun 2021 09:56:47

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

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 21:58:02

Generated On: 10 Jun 2021 09:56:47

---

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

Yes ☒

No ☐

---

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

---

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

Name of Medication JANUMENT

Prophylaxis Yes ☐  
No ☒

Indication DIABETES

Dose per administration 500-1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

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

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

Name of Medication PREGABALIN

Prophylaxis Yes ☐  
No ☒

Indication NEUROPATHY

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	05 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

Name of Medication FLUTICASONE

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" 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) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
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 (4)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

Name of Medication ADVAIR

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

Dose per administration 100/50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" 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) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
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 (5)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication REFLUX

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
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) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

Name of Medication SYNTHROID

Prophylaxis Yes ☐  
No ☒

Indication HYPOTHYROIDISM

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
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) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

Name of Medication EFFEXOR

Prophylaxis Yes ☐  
No ☒

Indication HORMONE REPLACEMENT  
THERAPY - POST MENOPAUSAL

Dose per administration 150

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

	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) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

Name of Medication CLOPIDOGREL

Prophylaxis Yes ☒  
No ☐

Indication STROKE PREVENTION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
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 (9)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

Name of Medication LOVAXA

Prophylaxis Yes ☐  
No ☒

Indication UNK

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☒  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☒  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

Name of Medication ROSUVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HIGH TRIGLYCERIDES

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
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) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

Name of Medication LOSARTAN

Prophylaxis Yes ☐  
No ☒

Indication HBP

Dose per administration 50

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

Name of Medication GLUCOSAMINE/CHONDROITIN

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 500/400

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 (12)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

Name of Medication FISH OIL

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☒  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☒  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

Name of Medication CITRUCEL

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 500

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☒  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

Name of Medication ELLURA

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 36

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 (15)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
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) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

Name of Medication CALCIUM

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 1200

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 (16)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
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 (17)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

Name of Medication VITAMIN B COMPLEX

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☒  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
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 (18)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

Name of Medication ZYRTEC

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

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 (18)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
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"/>

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

Name of Medication XYZAL

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 5

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
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"/>

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

Name of Medication ASPIRIN

Prophylaxis Yes ☐  
No ☒

Indication ATHEROSCLEROSIS OF AORTA

Dose per administration 81

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy) _____		
Start date completely unknown		True
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"/>

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

Name of Medication INFLUENZA

Prophylaxis Yes ☒  
No ☐

Indication VACCINE

Dose per administration UNK

Dose unit mg ☐  
ug ☐  
mL ☒  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		1 SEP 2019
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 1 SEP 2019		
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"/>

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

Name of Medication NITROFURANTOIN

Prophylaxis Yes ☐  
No ☒

Indication UTI

Dose per administration 100

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 (22)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		09 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

Name of Medication SALINE WITH MAGNESIUM

Prophylaxis Yes ☐  
No ☒

Indication DEHYDRATION - SAE

Dose per administration UNK

Dose unit mg ☐  
ug ☐  
mL ☒  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☒  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		27 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) 29 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
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 (24)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

Name of Medication ZICAM (ZINC ACETATE AND  
ZINC GLUCONATE)

Prophylaxis Yes ☐  
No ☒

Indication COMMON COLD

Dose per administration UNK

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☒  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 12 Apr 2021 00:10:06

Generated On: 10 Jun 2021 09:56:47

	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)		19 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3822278

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 21:58:02

Generated On: 10 Jun 2021 09:56:47

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3822278

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 02 Apr 2021 21:58:02

Generated On: 10 Jun 2021 09:56:47

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
27 SEP 2020	LUMBAR PUNCTURE	Diagnostic	

US3822278

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:56:47

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

US3822278

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:56:47

Date of study discontinuation/completion ( <i>dd MMM yyyy</i> )	
Reason for discontinuation	AE (specify) <input type="checkbox"/>
	SAE (specify) <input type="checkbox"/>
	Complete <input 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"/>
	Other <input type="checkbox"/>
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 <input type="checkbox"/>
	Unknown <input type="checkbox"/>
	Other <input type="checkbox"/>
If main cause of death is Other, specify	
Date of death ( <i>dd MMM yyyy</i> )	
Was autopsy performed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
	Unknown <input type="checkbox"/>

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 02 Apr 2021 21:58:02

Generated On: 10 Jun 2021 09:56:47

SAEID	USA-US126-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NC
Site Address: Postal Code	28210
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12



US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 02 Apr 2021 21:58:02

Generated On: 10 Jun 2021 09:56:47

SAEID	USA-US126-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NC
Site Address: Postal Code	28210
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	29/SEP/2020 09:37
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

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 02 Apr 2021 21:58:02

Generated On: 10 Jun 2021 09:56:47

SAEID	USA-US126-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NC
Site Address: Postal Code	28210
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	15/OCT/2020 08:05
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

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 02 Apr 2021 21:58:02

Generated On: 10 Jun 2021 09:56:47

SAEID	USA-US126-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NC
Site Address: Postal Code	28210
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	16/OCT/2020 12:51
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

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 02 Apr 2021 21:58:02

Generated On: 10 Jun 2021 09:56:47

SAEID	USA-US126-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NC
Site Address: Postal Code	28210
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	05/NOV/2020 13:36
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

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Data signed: (b) (4) 02 Apr 2021 21:58:02

Generated On: 10 Jun 2021 09:56:47

SAEID	USA-US126-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NC
Site Address: Postal Code	28210
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	06/NOV/2020 13:13
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

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Data signed: (b) (4) 02 Apr 2021 21:58:02

Generated On: 10 Jun 2021 09:56:47

SAEID	USA-US126-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NC
Site Address: Postal Code	28210
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	06/NOV/2020 13:22
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Data signed: (b) (4) 02 Apr 2021 21:58:02

Generated On: 10 Jun 2021 09:56:47

SAEID	USA-US126-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NC
Site Address: Postal Code	28210
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	12/NOV/2020 00:56
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.	True

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form (8)

Data signed: (b) (4) 02 Apr 2021 21:58:02

Generated On: 10 Jun 2021 09:56:47

SAEID	USA-US126-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NC
Site Address: Postal Code	28210
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	24/NOV/2020 14:48
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



US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form (9)

Data signed: (b) (4) 02 Apr 2021 21:58:02

Generated On: 10 Jun 2021 09:56:47

SAEID	USA-US126-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NC
Site Address: Postal Code	28210
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	24/NOV/2020 19:08
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

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form (10)

Data signed: (b) (4) 02 Apr 2021 21:58:02

Generated On: 10 Jun 2021 09:56:47

SAEID	USA-US126-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NC
Site Address: Postal Code	28210
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	04/JAN/2021 14:48
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

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form (11)

Data signed: (b) (4) 02 Apr 2021 21:58:02

Generated On: 10 Jun 2021 09:56:47

SAEID	USA-US126-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NC
Site Address: Postal Code	28210
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	08/FEB/2021 12:14
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

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form (12)

Data signed: (b) (4) 02 Apr 2021 21:58:02

Generated On: 10 Jun 2021 09:56:47

SAEID	USA-US126-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NC
Site Address: Postal Code	28210
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	08/FEB/2021 14:49
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000009

Form: Safety Report Form

Data signed: (b) (4) 02 Apr 2021 21:58:02

Generated On: 10 Jun 2021 09:56:47

SAEID	USA-US126-2020-MRNA-1273-P301000009
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NC
Site Address: Postal Code	28210
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Data signed: (b) (4) 02 Apr 2021 21:58:02

Generated On: 10 Jun 2021 09:56:47

SAEID	USA-US126-2020-MRNA-1273-P301000009
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NC
Site Address: Postal Code	28210
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	
Date of submission (Pre-filled from custom function)	02/OCT/2020 00:00
<b>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.</b>	

Audit

US3822278 (Prod: Tryon Medical Partners, PLLC)

**US3822278**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:56:47**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered 'US3822278'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 18:54:36



US3822278

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:56:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:54:14

US3822278

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:56:47

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '26 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 18:54:38

US3822278

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:56:47

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:54:14

US3822278

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:56:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered 'SCRN'	System	23 Sep 2020 15:54:14

US3822278

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:56:47

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered (b) (6) 1951'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 18:54:39

US3822278

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:56:47

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '69'	Kelly Woodell (b) (4)	02 Sep 2020 21:38:29

**US3822278**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:56:47**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered 'YEARS'	System	02 Sep 2020 21:38:29

**US3822278**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:56:47**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered '69'	System	26 Aug 2020 19:22:18



**US3822278**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:56:47**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'Female (F)'	Kelly Woodell (b) (4)	02 Sep 2020 21:38:29

US3822278

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:56:47

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Kelly Woodell (b) (4)	02 Sep 2020 21:38:29

US3822278

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:56:47

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'I'	Kelly Woodell (b) (4)	02 Sep 2020 21:38:29

US3822278

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:56:47

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '0'	Kelly Woodell (b) (4)	02 Sep 2020 21:38:29

US3822278

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:56:47

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '0'	Kelly Woodell (b) (4)	02 Sep 2020 21:38:29

US3822278

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:56:47

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '0'	Kelly Woodell (b) (4)	02 Sep 2020 21:38:29

US3822278

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:56:47

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '0'	Kelly Woodell (b) (4)	02 Sep 2020 21:38:29

US3822278

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:56:47

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '0'	Kelly Woodell (b) (4)	02 Sep 2020 21:38:29



US3822278

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:56:47

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered empty.	Kelly Woodell (b) (4)	02 Sep 2020 21:38:29

**US3822278**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:56:47**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '0'	Kelly Woodell (b) (4)	02 Sep 2020 21:38:29

US3822278

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:56:47

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '0'	Kelly Woodell (b) (4)	02 Sep 2020 21:38:29

US3822278

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:56:47

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '26 Aug 2020'	Kelly Woodell (b) (4)	26 Aug 2020 19:22:18

US3822278

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:56:47

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered 'Aug 2020'	System	26 Aug 2020 19:22:18

US3822278

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:56:47

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered '2020'	System	26 Aug 2020 19:22:18

US3822278

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:56:47

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'Amendment 2 (2)'	Kelly Woodell (b) (4)	26 Aug 2020 19:22:18

US3822278

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:56:47

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	26 Aug 2020 19:22:18



US3822278

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:56:47

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered empty.	Kelly Woodell (b) (4)	26 Aug 2020 19:22:18

US3822278

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:56:47

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered empty.	Kelly Woodell (b) (4)	26 Aug 2020 19:22:18

US3822278

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:56:47

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'No (N)'	Kelly Woodell (b) (4)	26 Aug 2020 19:22:18

US3822278

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:56:47

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 18:54:38

US3822278

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:56:47

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered 'I'	System	26 Aug 2020 19:22:22

US3822278

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:56:47

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	26 Aug 2020 19:22:22

US3822278

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:56:47

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:54:23

US3822278

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:56:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Diabetes mellitus, LLT: Diabetes - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 15:57:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 15:57:49
Data point term sent to Coder	System	23 Sep 2020 15:56:50
User entered 'Diabetes'	(b) (4), (b) (6)	23 Sep 2020 15:55:54



**US3822278**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:56:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:55:54

US3822278

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:56:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User entered 'I'	(b) (4), (b) (6)	23 Sep 2020 15:55:54

US3822278

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:56:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 15:55:54

US3822278

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:56:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:55:54

US3822278

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:56:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 15:55:54

US3822278

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:56:47

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered empty.	System	23 Sep 2020 15:55:54

US3822278

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:56:47

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered empty.	System	23 Sep 2020 15:55:54

US3822278

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:56:47

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered empty.	System	23 Sep 2020 15:55:54



US3822278

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:56:47

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered empty.	System	23 Sep 2020 15:55:54

US3822278

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:56:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 15:57:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 15:57:49
Data point term sent to Coder	System	23 Sep 2020 15:56:51
User entered 'Seasonal allergies'	(b) (4), (b) (6)	23 Sep 2020 15:56:35

US3822278

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:56:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:56:35

US3822278

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:56:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User entered 'I'	(b) (4), (b) (6)	23 Sep 2020 15:56:35

US3822278

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:56:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 15:56:35

US3822278

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:56:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:56:35

US3822278

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:56:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 15:56:35

US3822278

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:56:47

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered empty.	System	23 Sep 2020 15:56:35



US3822278

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:56:47

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered empty.	System	23 Sep 2020 15:56:35

US3822278

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:56:47

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered empty.	System	23 Sep 2020 15:56:35

US3822278

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:56:47

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered empty.	System	23 Sep 2020 15:56:35

US3822278

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:56:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 15:57:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 15:57:49
Data point term sent to Coder	System	23 Sep 2020 15:56:51
User entered 'Hypertension'	(b) (4), (b) (6)	23 Sep 2020 15:56:43

US3822278

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:56:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:56:43

US3822278

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:56:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User entered 'I'	(b) (4), (b) (6)	23 Sep 2020 15:56:43

US3822278

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:56:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 15:56:43

US3822278

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:56:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:56:43



US3822278

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:56:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 15:56:43

US3822278

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:56:47

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered empty.	System	23 Sep 2020 15:56:43

US3822278

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:56:47

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered empty.	System	23 Sep 2020 15:56:43

US3822278

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:56:47

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered empty.	System	23 Sep 2020 15:56:43

US3822278

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:56:47

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered empty.	System	23 Sep 2020 15:56:43

US3822278

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:56:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User coded data point as SOC: Vascular disorders, HLGT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Non-site specific necrosis and vascular insufficiency NEC, PT: Arteriosclerosis, LLT: Atherosclerosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 15:58:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 15:58:39
Data point term sent to Coder	System	23 Sep 2020 15:57:54
User entered 'Atherosclerosis'	(b) (4), (b) (6)	23 Sep 2020 15:57:12

US3822278

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:56:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:57:12

US3822278

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:56:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User entered 'I'	(b) (4), (b) (6)	23 Sep 2020 15:57:12



US3822278

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:56:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 15:57:12

US3822278

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:56:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:57:12

US3822278

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:56:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 15:57:12

US3822278

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:56:47

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered empty.	System	23 Sep 2020 15:57:12

US3822278

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:56:47

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered empty.	System	23 Sep 2020 15:57:12

US3822278

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:56:47

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered empty.	System	23 Sep 2020 15:57:12

US3822278

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:56:47

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered empty.	System	23 Sep 2020 15:57:12

US3822278

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:56:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 15:58:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 15:58:40
Data point term sent to Coder	System	23 Sep 2020 15:57:54
User entered 'Acid reflux'	(b) (4), (b) (6)	23 Sep 2020 15:57:29



**US3822278**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:56:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:57:29

US3822278

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:56:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User entered 'I'	(b) (4), (b) (6)	23 Sep 2020 15:57:29

US3822278

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:56:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 15:57:29

US3822278

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:56:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:57:29

US3822278

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:56:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 15:57:29

US3822278

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:56:47

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered empty.	System	23 Sep 2020 15:57:29

US3822278

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:56:47

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered empty.	System	23 Sep 2020 15:57:29

US3822278

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:56:47

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered empty.	System	23 Sep 2020 15:57:29



US3822278

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:56:47

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered empty.	System	23 Sep 2020 15:57:29

US3822278

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:56:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 16:03:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 16:03:39
Data point term sent to Coder	System	23 Sep 2020 16:03:07
User entered 'Asthma'	(b) (4), (b) (6)	23 Sep 2020 16:02:08

US3822278

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:56:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:02:08

US3822278

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:56:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User entered 'I'	(b) (4), (b) (6)	23 Sep 2020 16:02:08

US3822278

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:56:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 16:02:08

US3822278

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:56:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:02:08

US3822278

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:56:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 16:02:08

US3822278

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:56:47

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered empty.	System	23 Sep 2020 16:02:08



**US3822278**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:56:47**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered empty.	System	23 Sep 2020 16:02:08

US3822278

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:56:47

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered empty.	System	23 Sep 2020 16:02:08

US3822278

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:56:47

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered empty.	System	23 Sep 2020 16:02:08

US3822278

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:56:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User coded data point as SOC: Investigations, HLGT: Lipid analyses, HLT: Triglyceride analyses, PT: Blood triglycerides increased, LLT: Triglycerides high - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:51:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:51:35
Data point term sent to Coder	System	05 Nov 2020 16:50:42
User entered 'HIGH TRIGLYCERIDES'	(b) (4), (b) (6)	05 Nov 2020 16:50:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:50:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	23 Sep 2020 17:43:52

US3822278

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:56:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 16:50:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:50:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	23 Sep 2020 17:43:52

US3822278

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:56:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User entered 'I'	(b) (4), (b) (6)	05 Nov 2020 16:50:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:50:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	23 Sep 2020 17:43:52

US3822278

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:56:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 16:50:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:50:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	23 Sep 2020 17:43:52

US3822278

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:56:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 16:50:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:50:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	23 Sep 2020 17:43:52



US3822278

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:56:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 16:50:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:50:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	23 Sep 2020 17:43:52

US3822278

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:56:47

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered empty.	System	05 Nov 2020 16:50:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:50:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	23 Sep 2020 17:43:52

US3822278

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:56:47

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered empty.	System	05 Nov 2020 16:50:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:50:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	23 Sep 2020 17:43:52

US3822278

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:56:47

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered empty.	System	05 Nov 2020 16:50:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:50:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	23 Sep 2020 17:43:52

US3822278

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:56:47

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered empty.	System	05 Nov 2020 16:50:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	05 Nov 2020 16:50:18
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	23 Sep 2020 17:43:52

US3822278

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:56:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 22:09:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 22:09:31
Data point term sent to Coder	System	20 Oct 2020 22:09:07
User entered 'post menopausal'	Kelly Woodell (b) (4) (b) (4)	20 Oct 2020 22:08:58

US3822278

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:56:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User entered 'un Jan 2005'	Kelly Woodell (b) (4) (b) (4)	20 Oct 2020 22:08:58

US3822278

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:56:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User entered '0'	Kelly Woodell (b) (4) (b) (4)	20 Oct 2020 22:08:58



US3822278

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:56:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User entered 'Yes (Y)'	Kelly Woodell (b) (4) (b) (4)	20 Oct 2020 22:08:58

US3822278

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:56:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User entered empty.	Kelly Woodell (b) (4) (b) (4)	20 Oct 2020 22:08:58

US3822278

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:56:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:17
User entered '0'	Kelly Woodell (b) (4) (b) (4)	20 Oct 2020 22:08:58

US3822278

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:56:47

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered 'Jan 2005'	System	20 Oct 2020 22:08:58

US3822278

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:56:47

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered '2005'	System	20 Oct 2020 22:08:58

US3822278

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:56:47

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered empty.	System	20 Oct 2020 22:08:58

US3822278

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:56:47

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered empty.	System	20 Oct 2020 22:08:58

US3822278

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:56:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	05 Feb 2021 15:04:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Feb 2021 15:04:42
Data point term sent to Coder	System	05 Feb 2021 15:04:05
User entered 'hypothyroidism'	(b) (4), (b) (6)	05 Feb 2021 15:03:47



US3822278

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:56:47

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:03:47

US3822278

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:56:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'I'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:03:47

US3822278

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:56:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:03:47

US3822278

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:56:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:03:47

US3822278

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:56:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:03:47

US3822278

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:56:47

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered empty.	System	05 Feb 2021 15:03:47

US3822278

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:56:47

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered empty.	System	05 Feb 2021 15:03:47

US3822278

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:56:47

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered empty.	System	05 Feb 2021 15:03:47



**US3822278**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:56:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered empty.	System	05 Feb 2021 15:03:47

US3822278

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Oct 2020 22:08:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Kelly Woodell (b) (4)	20 Oct 2020 22:08:09
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	23 Sep 2020 15:54:54
	(b) (4), (b) (6)	23 Sep 2020 15:54:54

US3822278

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '26 Aug 2020' reason for change: Data Entry Error	(b) (4)	20 Oct 2020 22:08:09
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:54:54

US3822278

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '14:40' reason for change: Data Entry Error	Kelly Woodell (b) (4)	20 Oct 2020 22:08:09
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 15:54:54

US3822278

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered '26 Aug 2020 14:40'	System	20 Oct 2020 22:08:09
User entered empty.	System	23 Sep 2020 15:54:54

US3822278

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '63' in	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:54:54
DataPoint set to visible.	System	26 Aug 2020 19:22:22

US3822278

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '150' lb	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:54:54
DataPoint set to visible.	System	26 Aug 2020 19:22:22

US3822278

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered '26.62687'	System	23 Sep 2020 15:54:54
DataPoint set to visible.	System	26 Aug 2020 19:22:22



US3822278

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered 'kg/m2'	System	23 Sep 2020 15:54:54
DataPoint set to visible.	System	26 Aug 2020 19:22:22

US3822278

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:54:54

US3822278

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:54:54

US3822278

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:54:54

US3822278

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:54:54

US3822278

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered 'bpm'	System	23 Sep 2020 15:54:54

US3822278

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:54:54

US3822278

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered 'breaths/min'	System	23 Sep 2020 15:54:54



US3822278

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:54:54

US3822278

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered 'mmHg'	System	23 Sep 2020 15:54:54

US3822278

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:54:54

US3822278

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered 'mmHg'	System	23 Sep 2020 15:54:54

US3822278

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10

US3822278

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10

US3822278

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:56:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:44:23

US3822278

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:56:47

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:44:23



US3822278

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:56:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:44:57

US3822278

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:56:47

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:44:57

US3822278

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:56:47

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:46:51
Query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' answered with 'added' (Site from DM).	Kelly Woodell (b) (4) (b) (4)	20 Oct 2020 22:08:27
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 14:15:10
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4), (b) (6)	23 Sep 2020 17:44:57

US3822278

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:56:47

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:44:57

US3822278

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:56:47

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:44:57

US3822278

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:56:47

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:44:57

US3822278

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:56:47

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'UN Jan 2005'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:44:57

US3822278

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:56:47

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:44:57



US3822278

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:47

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:47

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:47

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:47

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:26

US3822278

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:47

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:47

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:47

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:47

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:26



US3822278

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:47

**Hospitality and Tourism Workers** (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:26

US3822278

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:47

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:26

US3822278

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:47

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:47

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:47

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:47

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:26

US3822278

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:47

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:26

US3822278

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:47

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:26



US3822278

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:47

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:26

US3822278

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:47

**Resides in low density, multi-family setting without** (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:26

US3822278

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:47

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:26

US3822278

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:47

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:26

US3822278

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:56:47

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:26

US3822278

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:56:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:38

US3822278

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:56:47

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 25SEP2020 is reported under Visit 2 Day 29 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)	23 Nov 2020 14:14:45
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 25SEP2020 is reported under Visit 2 Day 29 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 'All V2 data has been entered' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 15:10:01
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 25SEP2020 is reported under Visit 2 Day 29 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)	02 Nov 2020 12:35:30
User entered '26 Aug 2020'	(b) (4), (b) (6)	23 Sep 2020 17:45:38

US3822278

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:56:47

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:45:38



US3822278

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:56:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered 'VISIT1'	System	23 Sep 2020 17:45:38

US3822278

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:56:47

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '26 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 18:54:43

US3822278

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:56:47

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '188253'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 18:54:43

US3822278

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:56:47

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 18:54:43

US3822278

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:56:47

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User closed query 'PER CDM: Please complete this section of the form.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 11:35:05
Query 'PER CDM: Please complete this section of the form.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 16:18:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 16:18:16
User opened query 'PER CDM: Please complete this section of the form.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 12:08:50

US3822278

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:56:47

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:18:16

US3822278

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:56:47

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:18:16

US3822278

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:56:47

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:18:16



US3822278

Folder: Visit 1 Day 1

Form: Randomization

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[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:18:16

US3822278

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:56:47

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:18:16
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:47:14
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:06:47

US3822278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:56:47

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:46:55

US3822278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:56:47

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:46:55

US3822278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:56:47

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:46:55

US3822278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:56:47

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:46:55

US3822278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	23 Sep 2020 17:46:55

US3822278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:46:55



US3822278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:46:55

US3822278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '14:40'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:46:55

US3822278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered '26 Aug 2020 14:40'	System	23 Sep 2020 17:46:55

US3822278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '98.3' F	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:46:55

US3822278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:46:55

US3822278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:46:55

US3822278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '72'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:46:55

US3822278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered 'bpm'	System	23 Sep 2020 17:46:55



US3822278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '16'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:46:55

US3822278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered 'breaths/min'	System	23 Sep 2020 17:46:55

US3822278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '110'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:46:55

US3822278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered 'mmHg'	System	23 Sep 2020 17:46:55

US3822278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:47

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '68'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:46:55

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered 'mmHg'	System	23 Sep 2020 17:46:55

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:56:47

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:46:55

US3822278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:56:47

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:46:55



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	23 Sep 2020 17:46:55

US3822278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:46:55

US3822278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:46:55

US3822278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '15:45'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:46:55

US3822278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered '26 Aug 2020 15:45'	System	23 Sep 2020 17:46:55

US3822278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '98.3' F	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:46:55

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:46:55

US3822278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:46:55



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '72'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:46:55

US3822278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered 'bpm'	System	23 Sep 2020 17:46:55

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '18'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:46:55

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered 'breaths/min'	System	23 Sep 2020 17:46:55

US3822278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '124'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:46:55

US3822278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered 'mmHg'	System	23 Sep 2020 17:46:55

US3822278

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '76'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:46:55

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered 'mmHg'	System	23 Sep 2020 17:46:55



US3822278

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:56:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:47:00

US3822278

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:56:47

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:47:00

US3822278

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:56:47

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	26 Aug 2020 19:23:43

US3822278

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:56:47

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered empty.	Kelly Woodell (b) (4)	26 Aug 2020 19:23:43

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:56:47

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered empty.	Kelly Woodell (b) (4)	26 Aug 2020 19:23:43

US3822278

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:56:47

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered 'MRNA-1273 OR PLACEBO'	System	26 Aug 2020 19:23:43

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:56:47

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '26 Aug 2020'	Kelly Woodell (b) (4)	26 Aug 2020 19:23:43

US3822278

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:56:47

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '15:15'	Kelly Woodell (b) (4)	26 Aug 2020 19:23:43



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Folder: Visit 1 Day 1

Form: Exposure

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[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered '26 Aug 2020 15:15'	System	26 Aug 2020 19:23:43

US3822278

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:56:47

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'Right Arm (RIGHT ARM)'	Kelly Woodell (b) (4)	26 Aug 2020 19:23:43

US3822278

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:56:47

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered 'ONCE'	System	26 Aug 2020 19:23:43

US3822278

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:56:47

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered 'INTRAMUSCULAR'	System	26 Aug 2020 19:23:43

US3822278

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:47:13

US3822278

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:47:13

US3822278

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '14:50'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:47:13

US3822278

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered '26 Aug 2020 14:50'	System	23 Sep 2020 17:47:13



US3822278

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:56:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:49:26

US3822278

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:56:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	23 Sep 2020 17:49:26

US3822278

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:56:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:49:26

US3822278

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:56:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '12:07'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:49:26

US3822278

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:56:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered '26 Aug 2020 12:07'	System	23 Sep 2020 17:49:26

US3822278

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:56:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	23 Sep 2020 17:49:26

US3822278

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:56:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:49:26

US3822278

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:56:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:49:26



US3822278

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:56:47

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered empty.	System	23 Sep 2020 17:49:26

US3822278

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:56:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:49:33

US3822278

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:56:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered 'I'	System	23 Sep 2020 17:49:33

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	26 Aug 2020 19:23:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-26T15:36:21', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '9e98ebe4-210b-4339-872d-b7d1ded02b11' User entered 'Yes (Y)'	System	26 Aug 2020 19:36:37
	System	26 Aug 2020 19:36:37

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-26T15:36:01', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '9e98ebe4-210b-4339-872d-b7d1ded02b11' User entered '98.3'	System	26 Aug 2020 19:36:37
	System	26 Aug 2020 19:36:37

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-26T15:36:13', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '9e98ebe4-210b-4339-872d-b7d1ded02b11'	System	26 Aug 2020 19:36:37
User entered 'No (N)'	System	26 Aug 2020 19:36:37

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-26T15:36:30', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '9e98ebe4-210b-4339-872d-b7d1ded02b11' User entered '26 Aug 2020 15:36'	System	26 Aug 2020 19:36:37
	System	26 Aug 2020 19:36:37



US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '26 Aug 2020 15:35'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '26 Aug 2020 18:05'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	26 Aug 2020 19:23:43
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-27T00:48:24', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '3e2324a5-25d1-4f24-a6ca-4c165d3614d6' User entered 'Yes (Y)'	System	27 Aug 2020 04:49:02
	System	27 Aug 2020 04:49:02

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-27T00:48:44', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '3e2324a5-25d1-4f24-a6ca-4c165d3614d6' User entered '96.8'	System	27 Aug 2020 04:49:02
	System	27 Aug 2020 04:49:02

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-27T00:48:50', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '3e2324a5-25d1-4f24-a6ca-4c165d3614d6' User entered 'No (N)'	System	27 Aug 2020 04:49:02
	System	27 Aug 2020 04:49:02

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-27T00:49:00', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '3e2324a5-25d1-4f24-a6ca-4c165d3614d6' User entered '27 Aug 2020 00:49'	System	27 Aug 2020 04:49:02
	System	27 Aug 2020 04:49:02

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '26 Aug 2020 19:00'	System	26 Aug 2020 19:23:43



US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	26 Aug 2020 19:23:43
User entered 'Day 2'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:56:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-27T19:03:35', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'c8c4341f-d4af-4fe9-b31c-eea2e5ddab13' User entered 'Yes (Y)'	System	27 Aug 2020 23:05:04
	System	27 Aug 2020 23:05:04

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:56:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-27T19:04:38', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'c8c4341f-d4af-4fe9-b31c-eea2e5ddab13' User entered '97.4'	System	27 Aug 2020 23:05:04
	System	27 Aug 2020 23:05:04

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:56:47

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-27T19:04:43', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'c8c4341f-d4af-4fe9-b31c-eea2e5ddab13'	System	27 Aug 2020 23:05:04
User entered 'Yes (Y)'	System	27 Aug 2020 23:05:04

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:56:47

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Per day 8 source no new medication was taken' (Site from System).	(b) (4), (b) (6)	20 Nov 2020 08:51:10
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Kelly Woodell (b) (4)	10 Nov 2020 22:14:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-27T19:04:50', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'c8c4341f-d4af-4fe9-b31c-eea2e5ddab13'	System	27 Aug 2020 23:05:04
User entered '1'	System	27 Aug 2020 23:05:04

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:56:47

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-27T19:04:50', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'c8c4341f-d4af-4fe9-b31c-eea2e5ddab13' User entered '0'	System	27 Aug 2020 23:05:04
	System	27 Aug 2020 23:05:04

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:56:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-27T19:05:02', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'c8c4341f-d4af-4fe9-b31c-eea2e5ddab13'	System	27 Aug 2020 23:05:04
User entered '27 Aug 2020 19:05'	System	27 Aug 2020 23:05:04



US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	26 Aug 2020 19:23:43
User entered 'Day 3'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:56:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-28T21:50:23', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'fc151a20-d700-4d42-8a7c-d368461b49c6' User entered 'Yes (Y)'	System	29 Aug 2020 01:50:57
	System	29 Aug 2020 01:50:57

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:56:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-28T21:50:34', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'fc151a20-d700-4d42-8a7c-d368461b49c6' User entered '96.1'	System	29 Aug 2020 01:50:57
	System	29 Aug 2020 01:50:57

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:56:47

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-28T21:50:43', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'fc151a20-d700-4d42-8a7c-d368461b49c6' User entered 'No (N)'	System	29 Aug 2020 01:50:57
	System	29 Aug 2020 01:50:57

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:56:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-28T21:50:52', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'fc151a20-d700-4d42-8a7c-d368461b49c6' User entered '28 Aug 2020 21:50'	System	29 Aug 2020 01:50:57
	System	29 Aug 2020 01:50:57

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 19:23:43



US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	26 Aug 2020 19:23:43
User entered 'Day 4'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:56:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-30T00:02:39', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '27b2f744-27f5-4d65-9066-7e1cd220f0bf' User entered 'Yes (Y)'	System	30 Aug 2020 04:06:55
	System	30 Aug 2020 04:06:55

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:56:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-30T00:06:10', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '27b2f744-27f5-4d65-9066-7e1cd220f0bf' User entered '98.0'	System	30 Aug 2020 04:06:55
	System	30 Aug 2020 04:06:55

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:56:47

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-30T00:06:42', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '27b2f744-27f5-4d65-9066-7e1cd220f0bf'	System	30 Aug 2020 04:06:55
User entered 'No (N)'	System	30 Aug 2020 04:06:55

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:56:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-30T00:06:53', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '27b2f744-27f5-4d65-9066-7e1cd220f0bf' User entered '30 Aug 2020 00:06'	System	30 Aug 2020 04:06:55
	System	30 Aug 2020 04:06:55

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 19:23:43



US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	26 Aug 2020 19:23:43
User entered 'Day 5'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:56:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-30T16:16:20', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'db447474-5602-4a55-a84e-7b8dd310c0b7'	System	30 Aug 2020 20:16:40
User entered 'Yes (Y)'	System	30 Aug 2020 20:16:40

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:56:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-30T16:16:27', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'db447474-5602-4a55-a84e-7b8dd310c0b7' User entered '97.2'	System	30 Aug 2020 20:16:40
	System	30 Aug 2020 20:16:40

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:56:47

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-30T16:16:31', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'db447474-5602-4a55-a84e-7b8dd310c0b7'	System	30 Aug 2020 20:16:40
User entered 'No (N)'	System	30 Aug 2020 20:16:40

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:56:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-30T16:16:36', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'db447474-5602-4a55-a84e-7b8dd310c0b7' User entered '30 Aug 2020 16:16'	System	30 Aug 2020 20:16:40
	System	30 Aug 2020 20:16:40

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	26 Aug 2020 19:23:43
User entered 'Day 6'	System	26 Aug 2020 19:23:43



US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:56:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-31T19:10:51', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'e162b014-1d0f-47a8-baf1-0979b6f30d07' User entered 'Yes (Y)'	System	31 Aug 2020 23:11:16
	System	31 Aug 2020 23:11:16

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:56:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-31T19:10:57', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'e162b014-1d0f-47a8-baf1-0979b6f30d07' User entered '96.7'	System	31 Aug 2020 23:11:16
	System	31 Aug 2020 23:11:16

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:56:47

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-31T19:11:06', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'e162b014-1d0f-47a8-baf1-0979b6f30d07'	System	31 Aug 2020 23:11:16
User entered 'No (N)'	System	31 Aug 2020 23:11:16

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:56:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-31T19:11:12', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'e162b014-1d0f-47a8-baf1-0979b6f30d07'	System	31 Aug 2020 23:11:16
User entered '31 Aug 2020 19:11'	System	31 Aug 2020 23:11:16

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	26 Aug 2020 19:23:43
User entered 'Day 7'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:56:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39



US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:56:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:56:47

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:56:47

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:56:47

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:56:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	26 Aug 2020 19:23:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 19:23:43



US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-26T15:36:46', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '15752cfb-7abc-4e3f-af1d-52f3b7952c96'	System	26 Aug 2020 19:37:42
User entered 'None (1)'	System	26 Aug 2020 19:37:42

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-26T15:37:12', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '15752cfb-7abc-4e3f-af1d-52f3b7952c96'	System	26 Aug 2020 19:37:42
User entered 'No (N)'	System	26 Aug 2020 19:37:42

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-26T15:37:20', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '15752cfb-7abc-4e3f-af1d-52f3b7952c96'	System	26 Aug 2020 19:37:42
User entered 'No (N)'	System	26 Aug 2020 19:37:42

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-26T15:37:28', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '15752cfb-7abc-4e3f-af1d-52f3b7952c96'	System	26 Aug 2020 19:37:42
User entered 'None (1)'	System	26 Aug 2020 19:37:42

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-26T15:37:38', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '15752cfb-7abc-4e3f-af1d-52f3b7952c96' User entered '26 Aug 2020 15:37'	System	26 Aug 2020 19:37:42
	System	26 Aug 2020 19:37:42

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '26 Aug 2020 15:35'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '26 Aug 2020 18:05'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	26 Aug 2020 19:23:43
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 19:23:43



US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-27T00:49:10', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '46bd4606-8d22-4217-92de-b2cbbf62532a' User entered 'None (1)'	System	27 Aug 2020 04:49:35
	System	27 Aug 2020 04:49:35

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-27T00:49:15', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '46bd4606-8d22-4217-92de-b2cbbf62532a' User entered 'No (N)'	System	27 Aug 2020 04:49:35
	System	27 Aug 2020 04:49:35

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-27T00:49:20', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '46bd4606-8d22-4217-92de-b2cbbf62532a' User entered 'No (N)'	System	27 Aug 2020 04:49:35
	System	27 Aug 2020 04:49:35

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-27T00:49:28', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '46bd4606-8d22-4217-92de-b2cbbf62532a' User entered 'None (1)'	System	27 Aug 2020 04:49:35
	System	27 Aug 2020 04:49:35

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-27T00:49:32', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '46bd4606-8d22-4217-92de-b2cbbf62532a' User entered '27 Aug 2020 00:49'	System	27 Aug 2020 04:49:35
	System	27 Aug 2020 04:49:35

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '26 Aug 2020 19:00'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	26 Aug 2020 19:23:43
User entered 'Day 2'	System	26 Aug 2020 19:23:43



US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:56:47

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-27T17:47:29', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '7bfec27f-2ccd-43b9-8c5d-1adec58d45c4'	System	27 Aug 2020 23:08:04
User entered 'Any use of prescription pain reliever or System prevents daily activity (4)'		27 Aug 2020 23:08:04

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:56:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-27T17:47:24', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '7bfec27f-2ccd-43b9-8c5d-1adec58d45c4'	System	27 Aug 2020 23:08:04
User entered 'No (N)'	System	27 Aug 2020 23:08:04

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:56:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-27T19:07:43', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '7bfec27f-2ccd-43b9-8c5d-1adec58d45c4'	System	27 Aug 2020 23:08:04
User entered 'No (N)'	System	27 Aug 2020 23:08:04

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:56:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-27T19:07:50', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '7bfec27f-2ccd-43b9-8c5d-1adec58d45c4'	System	27 Aug 2020 23:08:04
User entered 'None (1)'	System	27 Aug 2020 23:08:04

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:56:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-27T19:08:03', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '7bfec27f-2ccd-43b9-8c5d-1adec58d45c4' User entered '27 Aug 2020 19:08'	System	27 Aug 2020 23:08:04
	System	27 Aug 2020 23:08:04

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	26 Aug 2020 19:23:43
User entered 'Day 3'	System	26 Aug 2020 19:23:43



US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:56:47

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-28T21:51:01', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'fbdc0df1-4924-40f4-90e1-203ac2ff2133'	System	29 Aug 2020 01:51:19
User entered 'Does not interfere with activity (2)'	System	29 Aug 2020 01:51:19

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:56:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-28T21:51:05', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'fbdc0df1-4924-40f4-90e1-203ac2ff2133'	System	29 Aug 2020 01:51:19
User entered 'No (N)'	System	29 Aug 2020 01:51:19

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:56:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-28T21:51:08', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'fbdc0df1-4924-40f4-90e1-203ac2ff2133'	System	29 Aug 2020 01:51:19
User entered 'No (N)'	System	29 Aug 2020 01:51:19

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:56:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-28T21:51:12', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'fbdc0df1-4924-40f4-90e1-203ac2ff2133'	System	29 Aug 2020 01:51:19
User entered 'None (1)'	System	29 Aug 2020 01:51:19

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:56:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-28T21:51:16', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'fbdc0df1-4924-40f4-90e1-203ac2ff2133'	System	29 Aug 2020 01:51:19
User entered '28 Aug 2020 21:51'	System	29 Aug 2020 01:51:19

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	26 Aug 2020 19:23:43
User entered 'Day 4'	System	26 Aug 2020 19:23:43



US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:56:47

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-30T00:07:03', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'c2d592f7-f321-407b-b3f0-7d1df3dd7333'	System	30 Aug 2020 04:07:28
User entered 'None (1)'	System	30 Aug 2020 04:07:28

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:56:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-30T00:07:08', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'c2d592f7-f321-407b-b3f0-7d1df3dd7333'	System	30 Aug 2020 04:07:28
User entered 'No (N)'	System	30 Aug 2020 04:07:28

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:56:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-30T00:07:12', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'c2d592f7-f321-407b-b3f0-7d1df3dd7333'	System	30 Aug 2020 04:07:28
User entered 'No (N)'	System	30 Aug 2020 04:07:28

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:56:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-30T00:07:17', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'c2d592f7-f321-407b-b3f0-7d1df3dd7333'	System	30 Aug 2020 04:07:28
User entered 'None (1)'	System	30 Aug 2020 04:07:28

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:56:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-30T00:07:24', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'c2d592f7-f321-407b-b3f0-7d1df3dd7333'	System	30 Aug 2020 04:07:28
User entered '30 Aug 2020 00:07'	System	30 Aug 2020 04:07:28

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	26 Aug 2020 19:23:43
User entered 'Day 5'	System	26 Aug 2020 19:23:43



US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:56:47

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-30T16:16:44', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '46d58839-38fa-4307-901f-1ce9bb77d589'	System	30 Aug 2020 20:16:59
User entered 'None (1)'	System	30 Aug 2020 20:16:59

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:56:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-30T16:16:47', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '46d58839-38fa-4307-901f-1ce9bb77d589'	System	30 Aug 2020 20:16:59
User entered 'No (N)'	System	30 Aug 2020 20:16:59

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:56:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-30T16:16:50', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '46d58839-38fa-4307-901f-1ce9bb77d589'	System	30 Aug 2020 20:16:59
User entered 'No (N)'	System	30 Aug 2020 20:16:59

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:56:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-30T16:16:53', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '46d58839-38fa-4307-901f-1ce9bb77d589' User entered 'None (1)'	System	30 Aug 2020 20:16:59
	System	30 Aug 2020 20:16:59

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:56:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-30T16:16:57', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '46d58839-38fa-4307-901f-1ce9bb77d589' User entered '30 Aug 2020 16:16'	System	30 Aug 2020 20:16:59
	System	30 Aug 2020 20:16:59

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	26 Aug 2020 19:23:43
User entered 'Day 6'	System	26 Aug 2020 19:23:43



US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:56:47

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-31T19:11:18', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '5c6c3b7e-42dc-4ad8-bf70-17f1451ece0b' User entered 'None (1)'	System	31 Aug 2020 23:11:43
	System	31 Aug 2020 23:11:43

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:56:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-31T19:11:23', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '5c6c3b7e-42dc-4ad8-bf70-17f1451ece0b' User entered 'No (N)'	System	31 Aug 2020 23:11:43
	System	31 Aug 2020 23:11:43

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:56:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-31T19:11:28', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '5c6c3b7e-42dc-4ad8-bf70-17f1451ece0b' User entered 'No (N)'	System	31 Aug 2020 23:11:43
	System	31 Aug 2020 23:11:43

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:56:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-31T19:11:35', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '5c6c3b7e-42dc-4ad8-bf70-17f1451ece0b' User entered 'None (1)'	System	31 Aug 2020 23:11:43
	System	31 Aug 2020 23:11:43

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:56:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-31T19:11:40', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '5c6c3b7e-42dc-4ad8-bf70-17f1451ece0b' User entered '31 Aug 2020 19:11'	System	31 Aug 2020 23:11:43
	System	31 Aug 2020 23:11:43

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	26 Aug 2020 19:23:43
User entered 'Day 7'	System	26 Aug 2020 19:23:43



US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:56:47

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:56:47

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:56:47

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)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:56:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:56:47

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:56:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:56:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 19:23:43



US3822278

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	26 Aug 2020 19:23:43
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-26T15:39:12', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'f817ed2d-9932-4234-a2f6-bb2f31704b97'	System	26 Aug 2020 19:39:50
User entered 'None (0)'	System	26 Aug 2020 19:39:50

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-26T15:39:15', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'f817ed2d-9932-4234-a2f6-bb2f31704b97'	System	26 Aug 2020 19:39:50
User entered 'None (0)'	System	26 Aug 2020 19:39:50

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-26T15:39:19', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'f817ed2d-9932-4234-a2f6-bb2f31704b97'	System	26 Aug 2020 19:39:50
User entered 'None (0)'	System	26 Aug 2020 19:39:50

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-26T15:39:22', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'f817ed2d-9932-4234-a2f6-bb2f31704b97' User entered 'None (0)'	System	26 Aug 2020 19:39:50
	System	26 Aug 2020 19:39:50

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-26T15:39:25', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'f817ed2d-9932-4234-a2f6-bb2f31704b97' User entered 'None (0)'	System	26 Aug 2020 19:39:50
	System	26 Aug 2020 19:39:50

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-26T15:39:28', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'f817ed2d-9932-4234-a2f6-bb2f31704b97'	System	26 Aug 2020 19:39:50
User entered 'None (0)'	System	26 Aug 2020 19:39:50



US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-26T15:39:36', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'f817ed2d-9932-4234-a2f6-bb2f31704b97'	System	26 Aug 2020 19:39:50
User entered 'No (N)'	System	26 Aug 2020 19:39:50

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-26T15:39:47', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'f817ed2d-9932-4234-a2f6-bb2f31704b97' User entered '26 Aug 2020 15:39'	System	26 Aug 2020 19:39:50
	System	26 Aug 2020 19:39:50

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '26 Aug 2020 15:35'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '26 Aug 2020 18:05'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	26 Aug 2020 19:23:43
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-27T00:49:44', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '19b664fb-eeda-4884-9233-27075518726f' User entered 'None (0)'	System	27 Aug 2020 04:50:17
	System	27 Aug 2020 04:50:17

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-27T00:49:48', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '19b664fb-eeda-4884-9233-27075518726f' User entered 'None (0)'	System	27 Aug 2020 04:50:17
	System	27 Aug 2020 04:50:17

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-27T00:49:52', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '19b664fb-eeda-4884-9233-27075518726f' User entered 'None (0)'	System	27 Aug 2020 04:50:17
	System	27 Aug 2020 04:50:17



US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-27T00:49:55', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '19b664fb-eeda-4884-9233-27075518726f' User entered 'None (0)'	System	27 Aug 2020 04:50:17
	System	27 Aug 2020 04:50:17

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-27T00:49:59', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '19b664fb-eeda-4884-9233-27075518726f' User entered 'None (0)'	System	27 Aug 2020 04:50:17
	System	27 Aug 2020 04:50:17

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-27T00:50:02', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '19b664fb-eeda-4884-9233-27075518726f' User entered 'None (0)'	System	27 Aug 2020 04:50:17
	System	27 Aug 2020 04:50:17

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-27T00:50:10', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '19b664fb-eeda-4884-9233-27075518726f' User entered 'No (N)'	System	27 Aug 2020 04:50:17
	System	27 Aug 2020 04:50:17

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-27T00:50:14', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '19b664fb-eeda-4884-9233-27075518726f' User entered '27 Aug 2020 00:50'	System	27 Aug 2020 04:50:17
	System	27 Aug 2020 04:50:17

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '26 Aug 2020 19:00'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	26 Aug 2020 19:23:43
User entered 'Day 2'	System	26 Aug 2020 19:23:43



US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-27T19:08:10', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '543ae0ce-e3e8-4580-ad1f-74375222318b' User entered 'None (0)'	System	27 Aug 2020 23:08:39
	System	27 Aug 2020 23:08:39

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-27T19:08:13', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '543ae0ce-e3e8-4580-ad1f-74375222318b' User entered 'None (0)'	System	27 Aug 2020 23:08:39
	System	27 Aug 2020 23:08:39

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-27T19:08:17', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '543ae0ce-e3e8-4580-ad1f-74375222318b' User entered 'None (0)'	System	27 Aug 2020 23:08:39
	System	27 Aug 2020 23:08:39

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-27T19:08:22', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '543ae0ce-e3e8-4580-ad1f-74375222318b' User entered 'None (0)'	System	27 Aug 2020 23:08:39
	System	27 Aug 2020 23:08:39

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-27T19:08:24', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '543ae0ce-e3e8-4580-ad1f-74375222318b' User entered 'None (0)'	System	27 Aug 2020 23:08:39
	System	27 Aug 2020 23:08:39

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-27T19:08:27', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '543ae0ce-e3e8-4580-ad1f-74375222318b' User entered 'None (0)'	System	27 Aug 2020 23:08:39
	System	27 Aug 2020 23:08:39

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:47

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-27T19:08:30', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '543ae0ce-e3e8-4580-ad1f-74375222318b' User entered 'No (N)'	System	27 Aug 2020 23:08:39
	System	27 Aug 2020 23:08:39

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-27T19:08:34', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '543ae0ce-e3e8-4580-ad1f-74375222318b' User entered '27 Aug 2020 19:08'	System	27 Aug 2020 23:08:39
	System	27 Aug 2020 23:08:39



US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	26 Aug 2020 19:23:43
User entered 'Day 3'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-28T21:51:32', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'd420ef75-0d7f-4fee-962e-381c35a3c43f' User entered 'None (0)'	System	29 Aug 2020 01:52:00
	System	29 Aug 2020 01:52:00

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-28T21:51:38', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'd420ef75-0d7f-4fee-962e-381c35a3c43f' User entered 'None (0)'	System	29 Aug 2020 01:52:00
	System	29 Aug 2020 01:52:00

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-28T21:51:41', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'd420ef75-0d7f-4fee-962e-381c35a3c43f' User entered 'None (0)'	System	29 Aug 2020 01:52:00
	System	29 Aug 2020 01:52:00

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-28T21:51:44', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'd420ef75-0d7f-4fee-962e-381c35a3c43f' User entered 'None (0)'	System	29 Aug 2020 01:52:00
	System	29 Aug 2020 01:52:00

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-28T21:51:47', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'd420ef75-0d7f-4fee-962e-381c35a3c43f' User entered 'None (0)'	System	29 Aug 2020 01:52:00
	System	29 Aug 2020 01:52:00



US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-28T21:51:50', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'd420ef75-0d7f-4fee-962e-381c35a3c43f' User entered 'None (0)'	System	29 Aug 2020 01:52:00
	System	29 Aug 2020 01:52:00

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:47

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-28T21:51:53', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'd420ef75-0d7f-4fee-962e-381c35a3c43f' User entered 'No (N)'	System	29 Aug 2020 01:52:00
	System	29 Aug 2020 01:52:00

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-28T21:51:57', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'd420ef75-0d7f-4fee-962e-381c35a3c43f' User entered '28 Aug 2020 21:51'	System	29 Aug 2020 01:52:00
	System	29 Aug 2020 01:52:00

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	26 Aug 2020 19:23:43
User entered 'Day 4'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-30T00:07:48', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '8001a719-d5e5-4bbf-b96e-5e12ce008d49'	System	30 Aug 2020 04:08:21
User entered 'No interference with activity (1)'	System	30 Aug 2020 04:08:21

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-30T00:07:54', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '8001a719-d5e5-4bbf-b96e-5e12ce008d49' User entered 'None (0)'	System	30 Aug 2020 04:08:21
	System	30 Aug 2020 04:08:21



US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-30T00:07:57', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '8001a719-d5e5-4bbf-b96e-5e12ce008d49' User entered 'None (0)'	System	30 Aug 2020 04:08:21
	System	30 Aug 2020 04:08:21

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-30T00:08:02', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '8001a719-d5e5-4bbf-b96e-5e12ce008d49' User entered 'None (0)'	System	30 Aug 2020 04:08:21
	System	30 Aug 2020 04:08:21

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-30T00:08:06', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '8001a719-d5e5-4bbf-b96e-5e12ce008d49' User entered 'None (0)'	System	30 Aug 2020 04:08:21
	System	30 Aug 2020 04:08:21

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-30T00:08:09', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '8001a719-d5e5-4bbf-b96e-5e12ce008d49' User entered 'None (0)'	System	30 Aug 2020 04:08:21
	System	30 Aug 2020 04:08:21

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:47

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-30T00:08:13', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '8001a719-d5e5-4bbf-b96e-5e12ce008d49' User entered 'No (N)'	System	30 Aug 2020 04:08:21
	System	30 Aug 2020 04:08:21

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-30T00:08:18', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '8001a719-d5e5-4bbf-b96e-5e12ce008d49' User entered '30 Aug 2020 00:08'	System	30 Aug 2020 04:08:21
	System	30 Aug 2020 04:08:21

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 19:23:43



US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	26 Aug 2020 19:23:43
User entered 'Day 5'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-30T16:17:09', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'f822afce-d13f-49fa-a14a-bc00cd619294' User entered 'None (0)'	System	30 Aug 2020 20:17:37
	System	30 Aug 2020 20:17:37

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-30T16:17:13', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'f822afce-d13f-49fa-a14a-bc00cd619294' User entered 'None (0)'	System	30 Aug 2020 20:17:37
	System	30 Aug 2020 20:17:37

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-30T16:17:16', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'f822afce-d13f-49fa-a14a-bc00cd619294' User entered 'None (0)'	System	30 Aug 2020 20:17:37
	System	30 Aug 2020 20:17:37

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-30T16:17:19', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'f822afce-d13f-49fa-a14a-bc00cd619294' User entered 'None (0)'	System	30 Aug 2020 20:17:37
	System	30 Aug 2020 20:17:37

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-30T16:17:22', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'f822afce-d13f-49fa-a14a-bc00cd619294' User entered 'None (0)'	System	30 Aug 2020 20:17:37
	System	30 Aug 2020 20:17:37

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-30T16:17:25', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'f822afce-d13f-49fa-a14a-bc00cd619294' User entered 'None (0)'	System	30 Aug 2020 20:17:37
	System	30 Aug 2020 20:17:37

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:47

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-30T16:17:31', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'f822afce-d13f-49fa-a14a-bc00cd619294' User entered 'No (N)'	System	30 Aug 2020 20:17:37
	System	30 Aug 2020 20:17:37



US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-30T16:17:34', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'f822afce-d13f-49fa-a14a-bc00cd619294' User entered '30 Aug 2020 16:17'	System	30 Aug 2020 20:17:37
	System	30 Aug 2020 20:17:37

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	26 Aug 2020 19:23:43
User entered 'Day 6'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-31T19:11:48', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '1684b51a-1793-4d7a-8727-526b814b5954' User entered 'None (0)'	System	31 Aug 2020 23:12:37
	System	31 Aug 2020 23:12:37

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-31T19:11:53', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '1684b51a-1793-4d7a-8727-526b814b5954' User entered 'None (0)'	System	31 Aug 2020 23:12:37
	System	31 Aug 2020 23:12:37

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-31T19:11:58', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '1684b51a-1793-4d7a-8727-526b814b5954' User entered 'None (0)'	System	31 Aug 2020 23:12:37
	System	31 Aug 2020 23:12:37

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-31T19:12:04', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '1684b51a-1793-4d7a-8727-526b814b5954' User entered 'None (0)'	System	31 Aug 2020 23:12:37
	System	31 Aug 2020 23:12:37



US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-31T19:12:17', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '1684b51a-1793-4d7a-8727-526b814b5954' User entered 'None (0)'	System	31 Aug 2020 23:12:37
	System	31 Aug 2020 23:12:37

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-31T19:12:26', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '1684b51a-1793-4d7a-8727-526b814b5954' User entered 'None (0)'	System	31 Aug 2020 23:12:37
	System	31 Aug 2020 23:12:37

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:47

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-31T19:12:29', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '1684b51a-1793-4d7a-8727-526b814b5954'	System	31 Aug 2020 23:12:37
User entered 'No (N)'	System	31 Aug 2020 23:12:37

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F7913B46-5128-491D-AE3D-245E5A267857)', Time: '2020-08-31T19:12:33', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '1684b51a-1793-4d7a-8727-526b814b5954' User entered '31 Aug 2020 19:12'	System	31 Aug 2020 23:12:37
	System	31 Aug 2020 23:12:37

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	26 Aug 2020 19:23:43
User entered 'Day 7'	System	26 Aug 2020 19:23:43

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39



US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:47

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 19:23:43



US3822278

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 19:23:43

US3822278

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:53:05

US3822278

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '4 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:53:05

US3822278

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:53:05

US3822278

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:53:05

US3822278

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:53:08

US3822278

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered 'I'	System	23 Sep 2020 17:53:08

US3822278

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:53:18



US3822278

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:19
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:53:18

US3822278

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:53:18

US3822278

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:19
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:53:18

US3822278

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:53:22

US3822278

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered 'I'	System	23 Sep 2020 17:53:22

US3822278

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:19
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 25SEP2020 is reported under Visit 2 Day 29visit 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)	27 Nov 2020 08:43:48
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 25SEP2020 is reported under Visit 2 Day 29visit 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 'All V2 data has been entered' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 15:11:37
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 25SEP2020 is reported under Visit 2 Day 29visit 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)	22 Oct 2020 07:49:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 17:53:32

US3822278

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:19
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:53:32

US3822278

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:53:32



US3822278

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:19
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:53:32

US3822278

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 17:54:04

US3822278

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered 'I'	System	23 Sep 2020 17:54:04

US3822278

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:56:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:58:01

US3822278

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:56:47

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '25 Sep 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:58:01

US3822278

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:56:47

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:58:01

US3822278

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:56:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered 'VISIT2'	System	05 Nov 2020 14:58:01

US3822278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	05 Nov 2020 14:58:52



US3822278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:58:52

US3822278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '25 Sep 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:58:52

US3822278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '14:06'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:58:52

US3822278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered '25 Sep 2020 14:06'	System	05 Nov 2020 14:58:52

US3822278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '97.7' F	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:58:52

US3822278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:58:52

US3822278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:58:52

US3822278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '67'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:58:52



US3822278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered 'bpm'	System	05 Nov 2020 14:58:52

US3822278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '18'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:58:52

US3822278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered 'breaths/min'	System	05 Nov 2020 14:58:52

US3822278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '123'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:58:52

US3822278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered 'mmHg'	System	05 Nov 2020 14:58:52

US3822278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:47

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '64'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:58:52

US3822278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:56:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered 'mmHg'	System	05 Nov 2020 14:58:52

US3822278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	05 Nov 2020 14:58:52



US3822278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:58:52

US3822278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '25 Sep 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:58:52

US3822278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '15:39'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:58:52

US3822278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered '25 Sep 2020 15:39'	System	05 Nov 2020 14:58:52

US3822278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '97.5' F	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:58:52

US3822278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:58:52

US3822278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:58:52

US3822278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '63'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:58:52



US3822278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered 'bpm'	System	05 Nov 2020 14:58:52

US3822278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '15'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:58:52

US3822278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered 'breaths/min'	System	05 Nov 2020 14:58:52

US3822278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '119'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:58:52

US3822278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered 'mmHg'	System	05 Nov 2020 14:58:52

US3822278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '63'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:58:52

US3822278

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:56:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered 'mmHg'	System	05 Nov 2020 14:58:52

US3822278

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:56:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:58:57



US3822278

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:56:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:58:57

US3822278

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:56:47

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User closed query 'Per GCL Lab Reconciliation: Swab sample has been received by Central Lab with date 25 Sep 2020. However Immunogenicity Assessment has not been filled out please confirm and update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 21:20:22
Query 'Per GCL Lab Reconciliation: Swab sample has been received by Central Lab with date 25 Sep 2020. However Immunogenicity Assessment has not been filled out please confirm and update accordingly. ' answered with 'V2 data has been entered' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 14:59:05
User opened query 'Per GCL Lab Reconciliation: Swab sample has been received by Central Lab with date 25 Sep 2020. However Immunogenicity Assessment has not been filled out please confirm and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 00:20:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 19:19:50

US3822278

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:56:47

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 19:19:50

US3822278

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:56:47

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 19:19:50

US3822278

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:56:47

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered 'MRNA-1273 OR PLACEBO'	System	25 Sep 2020 19:19:50

US3822278

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:56:47

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '25 Sep 2020'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 19:19:50

US3822278

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:56:47

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '15:08'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 19:19:50

US3822278

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:56:47

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered '25 Sep 2020 15:08'	System	25 Sep 2020 19:19:50



US3822278

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:56:47

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'Right Arm (RIGHT ARM)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 19:19:50

US3822278

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:56:47

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered 'ONCE'	System	25 Sep 2020 19:19:50

US3822278

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:56:47

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered 'INTRAMUSCULAR'	System	25 Sep 2020 19:19:50

US3822278

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:59:20

US3822278

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '25 Sep 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:59:20

US3822278

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '14:30'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:59:20

US3822278

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered '25 Sep 2020 14:30'	System	05 Nov 2020 14:59:20

US3822278

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:56:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '25 Sep 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:59:32



US3822278

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:56:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	05 Nov 2020 14:59:32

US3822278

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:56:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:59:32

US3822278

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:56:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '15:01'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:59:32

**US3822278**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:56:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered '25 Sep 2020 15:01'	System	05 Nov 2020 14:59:32

US3822278

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:56:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	05 Nov 2020 14:59:32

US3822278

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:56:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:59:32

US3822278

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:56:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:59:32

US3822278

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:56:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered empty.	System	05 Nov 2020 14:59:32



US3822278

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 14:59:35

US3822278

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered 'I'	System	05 Nov 2020 14:59:35

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	25 Sep 2020 19:19:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-25T15:40:52', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '296033a2-6004-454b-b0af-de215819f377'	System	25 Sep 2020 19:41:19
User entered 'Yes (Y)'	System	25 Sep 2020 19:41:19

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-25T15:41:02', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '296033a2-6004-454b-b0af-de215819f377' User entered '97.5'	System	25 Sep 2020 19:41:19
	System	25 Sep 2020 19:41:19

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-25T15:41:07', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '296033a2-6004-454b-b0af-de215819f377'	System	25 Sep 2020 19:41:19
User entered 'No (N)'	System	25 Sep 2020 19:41:19

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-25T15:41:18', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '296033a2-6004-454b-b0af-de215819f377'	System	25 Sep 2020 19:41:19
User entered '25 Sep 2020 15:41'	System	25 Sep 2020 19:41:19

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '25 Sep 2020 15:28'	System	25 Sep 2020 19:19:50



US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '25 Sep 2020 17:58'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	25 Sep 2020 19:19:50
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-25T21:41:43', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'c34babcd-242b-4215-9238-342eaab52992'	System	26 Sep 2020 01:41:56
User entered 'Yes (Y)'	System	26 Sep 2020 01:41:56

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-25T21:41:23', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'c34babcd-242b-4215-9238-342eaab52992'	System	26 Sep 2020 01:41:56
User entered '96.8'	System	26 Sep 2020 01:41:56

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-25T21:41:34', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'c34babcd-242b-4215-9238-342eaab52992'	System	26 Sep 2020 01:41:56
User entered 'No (N)'	System	26 Sep 2020 01:41:56

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-25T21:41:54', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'c34babcd-242b-4215-9238-342eaab52992'	System	26 Sep 2020 01:41:56
User entered '25 Sep 2020 21:41'	System	26 Sep 2020 01:41:56

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '25 Sep 2020 18:53'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 19:19:50



US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	25 Sep 2020 19:19:50
User entered 'Day 2'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:56:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:56:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:56:47

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:56:47

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:56:47

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:56:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 19:19:50



US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	25 Sep 2020 19:19:50
User entered 'Day 3'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:56:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-27T12:31:16', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'd6913649-e460-48df-b65d-f6cdd3ec1a45'	System	27 Sep 2020 16:33:22
User entered 'Yes (Y)'	System	27 Sep 2020 16:33:22

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:56:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-27T12:31:13', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'd6913649-e460-48df-b65d-f6cdd3ec1a45' User entered '96.4'	System	27 Sep 2020 16:33:22
	System	27 Sep 2020 16:33:22

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:56:47

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-27T12:31:21', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'd6913649-e460-48df-b65d-f6cdd3ec1a45'	System	27 Sep 2020 16:33:22
User entered 'Yes (Y)'	System	27 Sep 2020 16:33:22

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:56:47

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Conmed added' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 16:55:14
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-27T12:32:38', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'd6913649-e460-48df-b65d-f6cdd3ec1a45'	(b) (4), (b) (6)	05 Nov 2020 17:00:33
User entered '1'	System	27 Sep 2020 16:33:22
	System	27 Sep 2020 16:33:22
	System	27 Sep 2020 16:33:22

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:56:47

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-27T12:32:38', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'd6913649-e460-48df-b65d-f6cdd3ec1a45' User entered '0'	System	27 Sep 2020 16:33:22
	System	27 Sep 2020 16:33:22

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:56:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-27T12:33:18', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'd6913649-e460-48df-b65d-f6cdd3ec1a45'	System	27 Sep 2020 16:33:22
User entered '27 Sep 2020 12:33'	System	27 Sep 2020 16:33:22



US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	25 Sep 2020 19:19:50
User entered 'Day 4'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:56:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-29T00:57:34', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'f95fe19c-cd27-43e7-a7ea-960fb74ab5c7' User entered 'Yes (Y)'	System	29 Sep 2020 04:59:07
	System	29 Sep 2020 04:59:07

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:56:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-29T00:58:40', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'f95fe19c-cd27-43e7-a7ea-960fb74ab5c7' User entered '98.1'	System	29 Sep 2020 04:59:07
	System	29 Sep 2020 04:59:07

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:56:47

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-29T00:58:45', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'f95fe19c-cd27-43e7-a7ea-960fb74ab5c7'	System	29 Sep 2020 04:59:07
User entered 'Yes (Y)'	System	29 Sep 2020 04:59:07

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:56:47

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Conmed added' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 16:55:17
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-29T00:58:58', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'f95fe19c-cd27-43e7-a7ea-960fb74ab5c7'	(b) (4), (b) (6)	05 Nov 2020 17:00:25
User entered '1'	System	29 Sep 2020 04:59:07
	System	29 Sep 2020 04:59:07
	System	29 Sep 2020 04:59:07

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:56:47

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-29T00:58:58', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'f95fe19c-cd27-43e7-a7ea-960fb74ab5c7' User entered '0'	System	29 Sep 2020 04:59:07
	System	29 Sep 2020 04:59:07



US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:56:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-29T00:59:03', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'f95fe19c-cd27-43e7-a7ea-960fb74ab5c7' User entered '29 Sep 2020 00:59'	System	29 Sep 2020 04:59:07
	System	29 Sep 2020 04:59:07

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	25 Sep 2020 19:19:50
User entered 'Day 5'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:56:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-29T20:07:25', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '2f53ee04-f442-4ec1-ad8f-79832f221141' User entered 'Yes (Y)'	System	30 Sep 2020 00:09:18
	System	30 Sep 2020 00:09:18

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:56:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-29T20:08:49', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '2f53ee04-f442-4ec1-ad8f-79832f221141' User entered '98.3'	System	30 Sep 2020 00:09:18
	System	30 Sep 2020 00:09:18

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:56:47

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-29T20:08:55', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '2f53ee04-f442-4ec1-ad8f-79832f221141' User entered 'Yes (Y)'	System	30 Sep 2020 00:09:18
	System	30 Sep 2020 00:09:18

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:56:47

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Conmed added' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 16:55:20
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-29T20:09:06', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '2f53ee04-f442-4ec1-ad8f-79832f221141'	(b) (4), (b) (6)	05 Nov 2020 16:59:50
User entered '1'	System	30 Sep 2020 00:09:18
	System	30 Sep 2020 00:09:18
	System	30 Sep 2020 00:09:18



US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:56:47

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-29T20:09:06', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '2f53ee04-f442-4ec1-ad8f-79832f221141' User entered '0'	System	30 Sep 2020 00:09:18
	System	30 Sep 2020 00:09:18

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:56:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-29T20:09:13', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '2f53ee04-f442-4ec1-ad8f-79832f221141' User entered '29 Sep 2020 20:09'	System	30 Sep 2020 00:09:18
	System	30 Sep 2020 00:09:18

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	25 Sep 2020 19:19:50
User entered 'Day 6'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:56:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:56:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:56:47

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39



US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:56:47

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:56:47

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:56:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	25 Sep 2020 19:19:50
User entered 'Day 7'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:56:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-10-02T00:12:40', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'b1673f54-b5a2-4505-98ef-822beba93276' User entered 'Yes (Y)'	System	02 Oct 2020 04:14:30
	System	02 Oct 2020 04:14:30

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:56:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-10-02T00:14:06', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'b1673f54-b5a2-4505-98ef-822beba93276' User entered '97.8'	System	02 Oct 2020 04:14:30
	System	02 Oct 2020 04:14:30



US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:56:47

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-10-02T00:14:12', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'b1673f54-b5a2-4505-98ef-822beba93276'	System	02 Oct 2020 04:14:30
User entered 'No (N)'	System	02 Oct 2020 04:14:30

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:56:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-10-02T00:14:26', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'b1673f54-b5a2-4505-98ef-822beba93276' User entered '02 Oct 2020 00:14'	System	02 Oct 2020 04:14:30
	System	02 Oct 2020 04:14:30

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	25 Sep 2020 19:19:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-25T15:41:29', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '0e1af32b-1258-417e-9ba2-ec01b32bb5a0'	System	25 Sep 2020 19:42:03
User entered 'Does not interfere with activity (2)'	System	25 Sep 2020 19:42:03

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-25T15:41:38', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '0e1af32b-1258-417e-9ba2-ec01b32bb5a0' User entered 'No (N)'	System	25 Sep 2020 19:42:03
	System	25 Sep 2020 19:42:03

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-25T15:41:43', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '0e1af32b-1258-417e-9ba2-ec01b32bb5a0' User entered 'No (N)'	System	25 Sep 2020 19:42:03
	System	25 Sep 2020 19:42:03



US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-25T15:41:55', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '0e1af32b-1258-417e-9ba2-ec01b32bb5a0' User entered 'None (1)'	System	25 Sep 2020 19:42:03
	System	25 Sep 2020 19:42:03

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-25T15:42:00', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '0e1af32b-1258-417e-9ba2-ec01b32bb5a0' User entered '25 Sep 2020 15:42'	System	25 Sep 2020 19:42:03
	System	25 Sep 2020 19:42:03

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '25 Sep 2020 15:28'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '25 Sep 2020 17:58'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	25 Sep 2020 19:19:50
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-25T21:42:09', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '5074c750-f957-4783-b308-0fc22ca5bbec' User entered 'None (1)'	System	26 Sep 2020 01:43:35
	System	26 Sep 2020 01:43:35

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-25T21:43:14', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '5074c750-f957-4783-b308-0fc22ca5bbec' User entered 'No (N)'	System	26 Sep 2020 01:43:35
	System	26 Sep 2020 01:43:35

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-25T21:43:18', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '5074c750-f957-4783-b308-0fc22ca5bbec' User entered 'No (N)'	System	26 Sep 2020 01:43:35
	System	26 Sep 2020 01:43:35



US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-25T21:43:24', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '5074c750-f957-4783-b308-0fc22ca5bbec' User entered 'None (1)'	System	26 Sep 2020 01:43:35
	System	26 Sep 2020 01:43:35

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-25T21:43:33', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '5074c750-f957-4783-b308-0fc22ca5bbec' User entered '25 Sep 2020 21:43'	System	26 Sep 2020 01:43:35
	System	26 Sep 2020 01:43:35

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '25 Sep 2020 18:53'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	25 Sep 2020 19:19:50
User entered 'Day 2'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:56:47

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:56:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:56:47

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)	25 Feb 2021 19:45:39



US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:56:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:56:47

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:56:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:56:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	25 Sep 2020 19:19:50
User entered 'Day 3'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:56:47

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-27T12:34:03', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'e2a4719c-796a-467d-90d5-6ebedeea8caf'	System	27 Sep 2020 16:37:38
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	27 Sep 2020 16:37:38



US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:56:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-27T12:34:12', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'e2a4719c-796a-467d-90d5-6ebedeea8caf' User entered 'Yes (Y)'	System	27 Sep 2020 16:37:38
	System	27 Sep 2020 16:37:38

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:56:47

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)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-27T12:37:24', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'e2a4719c-796a-467d-90d5-6ebedeea8caf' User entered '2'	System	27 Sep 2020 16:37:38
	System	27 Sep 2020 16:37:38

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:56:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-27T12:36:13', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'e2a4719c-796a-467d-90d5-6ebedeea8caf' User entered 'Yes (Y)'	System	27 Sep 2020 16:37:38
	System	27 Sep 2020 16:37:38

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:56:47

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-27T12:36:36', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'e2a4719c-796a-467d-90d5-6ebedeea8caf' User entered '30'	System	27 Sep 2020 16:37:38
	System	27 Sep 2020 16:37:38

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:56:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-27T12:36:52', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'e2a4719c-796a-467d-90d5-6ebedeea8caf'	System	27 Sep 2020 16:37:38
User entered 'None (1)'	System	27 Sep 2020 16:37:38

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:56:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-27T12:37:35', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'e2a4719c-796a-467d-90d5-6ebedeea8caf' User entered '27 Sep 2020 12:37'	System	27 Sep 2020 16:37:38
	System	27 Sep 2020 16:37:38

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 19:19:50



US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	25 Sep 2020 19:19:50
User entered 'Day 4'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:56:47

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-29T00:59:13', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '2777782d-cb1f-4da3-93e4-fcee3023e1be' User entered 'None (1)'	System	29 Sep 2020 04:59:33
	System	29 Sep 2020 04:59:33

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:56:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-29T00:59:17', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '2777782d-cb1f-4da3-93e4-fcee3023e1be' User entered 'No (N)'	System	29 Sep 2020 04:59:33
	System	29 Sep 2020 04:59:33

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:56:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-29T00:59:21', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '2777782d-cb1f-4da3-93e4-fcee3023e1be' User entered 'No (N)'	System	29 Sep 2020 04:59:33
	System	29 Sep 2020 04:59:33

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:56:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-29T00:59:26', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '2777782d-cb1f-4da3-93e4-fcee3023e1be' User entered 'None (1)'	System	29 Sep 2020 04:59:33
	System	29 Sep 2020 04:59:33

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:56:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-29T00:59:31', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '2777782d-cb1f-4da3-93e4-fcee3023e1be' User entered '29 Sep 2020 00:59'	System	29 Sep 2020 04:59:33
	System	29 Sep 2020 04:59:33

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 19:19:50



US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	25 Sep 2020 19:19:50
User entered 'Day 5'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:56:47

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-29T20:09:19', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'eef3c2e3-df96-48b5-9c6f-e8e41ecae581'	System	30 Sep 2020 00:09:37
User entered 'None (1)'	System	30 Sep 2020 00:09:37

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:56:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-29T20:09:23', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'eef3c2e3-df96-48b5-9c6f-e8e41ecae581' User entered 'No (N)'	System	30 Sep 2020 00:09:37
	System	30 Sep 2020 00:09:37

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:56:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-29T20:09:26', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'eef3c2e3-df96-48b5-9c6f-e8e41ecae581' User entered 'No (N)'	System	30 Sep 2020 00:09:37
	System	30 Sep 2020 00:09:37

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:56:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-29T20:09:29', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'eef3c2e3-df96-48b5-9c6f-e8e41ecae581' User entered 'None (1)'	System	30 Sep 2020 00:09:37
	System	30 Sep 2020 00:09:37

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:56:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-29T20:09:33', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'eef3c2e3-df96-48b5-9c6f-e8e41ecae581' User entered '29 Sep 2020 20:09'	System	30 Sep 2020 00:09:37
	System	30 Sep 2020 00:09:37

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 19:19:50



US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	25 Sep 2020 19:19:50
User entered 'Day 6'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:56:47

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:56:47

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:56:47

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)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:56:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:56:47

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:56:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:56:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39



US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	25 Sep 2020 19:19:50
User entered 'Day 7'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:56:47

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-10-02T00:14:33', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'b876426a-7ec4-4f9d-abb9-378bcbae9065'	System	02 Oct 2020 04:14:54
User entered 'None (1)'	System	02 Oct 2020 04:14:54

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:56:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-10-02T00:14:38', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'b876426a-7ec4-4f9d-abb9-378bcbae9065' User entered 'No (N)'	System	02 Oct 2020 04:14:54
	System	02 Oct 2020 04:14:54

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:56:47

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-10-02T00:14:41', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'b876426a-7ec4-4f9d-abb9-378bcbae9065' User entered 'No (N)'	System	02 Oct 2020 04:14:54
	System	02 Oct 2020 04:14:54

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:56:47

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-10-02T00:14:46', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'b876426a-7ec4-4f9d-abb9-378bcbae9065'	System	02 Oct 2020 04:14:54
User entered 'None (1)'	System	02 Oct 2020 04:14:54

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:56:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-10-02T00:14:51', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'b876426a-7ec4-4f9d-abb9-378bcbae9065' User entered '02 Oct 2020 00:14'	System	02 Oct 2020 04:14:54
	System	02 Oct 2020 04:14:54



US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	25 Sep 2020 19:19:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-25T15:42:07', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '75ae8952-3aa9-40e0-a9ee-6a1fd1a80ee3' User entered 'None (0)'	System	25 Sep 2020 19:42:38
	System	25 Sep 2020 19:42:38

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-25T15:42:13', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '75ae8952-3aa9-40e0-a9ee-6a1fd1a80ee3' User entered 'None (0)'	System	25 Sep 2020 19:42:38
	System	25 Sep 2020 19:42:38

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-25T15:42:18', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '75ae8952-3aa9-40e0-a9ee-6a1fd1a80ee3' User entered 'None (0)'	System	25 Sep 2020 19:42:38
	System	25 Sep 2020 19:42:38

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-25T15:42:20', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '75ae8952-3aa9-40e0-a9ee-6a1fd1a80ee3' User entered 'None (0)'	System	25 Sep 2020 19:42:38
	System	25 Sep 2020 19:42:38

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-25T15:42:23', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '75ae8952-3aa9-40e0-a9ee-6a1fd1a80ee3' User entered 'None (0)'	System	25 Sep 2020 19:42:38
	System	25 Sep 2020 19:42:38



US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-25T15:42:28', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '75ae8952-3aa9-40e0-a9ee-6a1fd1a80ee3' User entered 'None (0)'	System	25 Sep 2020 19:42:38
	System	25 Sep 2020 19:42:38

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-25T15:42:32', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '75ae8952-3aa9-40e0-a9ee-6a1fd1a80ee3' User entered 'No (N)'	System	25 Sep 2020 19:42:38
	System	25 Sep 2020 19:42:38

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-25T15:42:36', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '75ae8952-3aa9-40e0-a9ee-6a1fd1a80ee3' User entered '25 Sep 2020 15:42'	System	25 Sep 2020 19:42:38
	System	25 Sep 2020 19:42:38

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '25 Sep 2020 15:28'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '25 Sep 2020 17:58'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	25 Sep 2020 19:19:50
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-25T21:44:11', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '1bfdcd70-a4b8-4f29-aaff-61b7e27e210b'	System	26 Sep 2020 01:45:04
User entered 'No interference with activity (1)'	System	26 Sep 2020 01:45:04

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-25T21:44:19', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '1bfdcd70-a4b8-4f29-aaff-61b7e27e210b' User entered 'None (0)'	System	26 Sep 2020 01:45:04
	System	26 Sep 2020 01:45:04



US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-25T21:44:31', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '1bfdcd70-a4b8-4f29-aaff-61b7e27e210b' User entered 'None (0)'	System	26 Sep 2020 01:45:04
	System	26 Sep 2020 01:45:04

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-25T21:44:40', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '1bfdcd70-a4b8-4f29-aaff-61b7e27e210b' User entered 'None (0)'	System	26 Sep 2020 01:45:04
	System	26 Sep 2020 01:45:04

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-25T21:44:44', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '1bfdcd70-a4b8-4f29-aaff-61b7e27e210b' User entered 'None (0)'	System	26 Sep 2020 01:45:04
	System	26 Sep 2020 01:45:04

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-25T21:44:48', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '1bfdcd70-a4b8-4f29-aaff-61b7e27e210b' User entered 'None (0)'	System	26 Sep 2020 01:45:04
	System	26 Sep 2020 01:45:04

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-25T21:44:53', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '1bfdcd70-a4b8-4f29-aaff-61b7e27e210b' User entered 'No (N)'	System	26 Sep 2020 01:45:04
	System	26 Sep 2020 01:45:04

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-25T21:44:59', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '1bfdcd70-a4b8-4f29-aaff-61b7e27e210b' User entered '25 Sep 2020 21:44'	System	26 Sep 2020 01:45:04
	System	26 Sep 2020 01:45:04

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '25 Sep 2020 18:53'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 19:19:50



US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	25 Sep 2020 19:19:50
User entered 'Day 2'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:47

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39



US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	25 Sep 2020 19:19:50
User entered 'Day 3'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-27T12:38:11', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '9e89a15d-2e55-4bc6-97ee-409c16e1b0aa'	System	27 Sep 2020 17:30:30
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	27 Sep 2020 17:30:30

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-27T13:29:41', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '9e89a15d-2e55-4bc6-97ee-409c16e1b0aa' User entered 'None (0)'	System	27 Sep 2020 17:30:30
	System	27 Sep 2020 17:30:30

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-27T12:38:50', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '9e89a15d-2e55-4bc6-97ee-409c16e1b0aa' User entered 'None (0)'	System	27 Sep 2020 17:30:30
	System	27 Sep 2020 17:30:30

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-27T12:39:02', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '9e89a15d-2e55-4bc6-97ee-409c16e1b0aa' User entered 'None (0)'	System	27 Sep 2020 17:30:30
	System	27 Sep 2020 17:30:30



US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-27T12:39:08', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '9e89a15d-2e55-4bc6-97ee-409c16e1b0aa' User entered 'None (0)'	System	27 Sep 2020 17:30:30
	System	27 Sep 2020 17:30:30

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-27T12:39:15', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '9e89a15d-2e55-4bc6-97ee-409c16e1b0aa' User entered 'None (0)'	System	27 Sep 2020 17:30:30
	System	27 Sep 2020 17:30:30

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:47

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-27T13:29:10', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '9e89a15d-2e55-4bc6-97ee-409c16e1b0aa' User entered 'Yes (Y)'	System	27 Sep 2020 17:30:30
	System	27 Sep 2020 17:30:30

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-27T13:30:28', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '9e89a15d-2e55-4bc6-97ee-409c16e1b0aa' User entered '27 Sep 2020 13:30'	System	27 Sep 2020 17:30:30
	System	27 Sep 2020 17:30:30

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	25 Sep 2020 19:19:50
User entered 'Day 4'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-29T00:59:39', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'a5465dc9-9156-442b-aecd-89873bcfae4f' User entered 'None (0)'	System	29 Sep 2020 05:00:25
	System	29 Sep 2020 05:00:25



US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-29T00:59:47', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'a5465dc9-9156-442b-aecd-89873bcfae4f' User entered 'None (0)'	System	29 Sep 2020 05:00:25
	System	29 Sep 2020 05:00:25

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-29T00:59:52', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'a5465dc9-9156-442b-aecd-89873bcfae4f' User entered 'None (0)'	System	29 Sep 2020 05:00:25
	System	29 Sep 2020 05:00:25

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-29T00:59:55', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'a5465dc9-9156-442b-aecd-89873bcfae4f' User entered 'None (0)'	System	29 Sep 2020 05:00:25
	System	29 Sep 2020 05:00:25

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-29T00:59:59', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'a5465dc9-9156-442b-aecd-89873bcfae4f' User entered 'None (0)'	System	29 Sep 2020 05:00:25
	System	29 Sep 2020 05:00:25

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-29T01:00:02', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'a5465dc9-9156-442b-aecd-89873bcfae4f' User entered 'None (0)'	System	29 Sep 2020 05:00:25
	System	29 Sep 2020 05:00:25

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:47

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-29T01:00:19', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'a5465dc9-9156-442b-aecd-89873bcfae4f' User entered 'Yes (Y)'	System	29 Sep 2020 05:00:25
	System	29 Sep 2020 05:00:25

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-29T01:00:23', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'a5465dc9-9156-442b-aecd-89873bcfae4f' User entered '29 Sep 2020 01:00'	System	29 Sep 2020 05:00:25
	System	29 Sep 2020 05:00:25

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 19:19:50



US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	25 Sep 2020 19:19:50
User entered 'Day 5'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-29T20:09:43', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'd643917c-7a20-493a-90f0-a97264a1fc37' User entered 'None (0)'	System	30 Sep 2020 00:10:14
	System	30 Sep 2020 00:10:14

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-29T20:09:49', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'd643917c-7a20-493a-90f0-a97264a1fc37' User entered 'None (0)'	System	30 Sep 2020 00:10:14
	System	30 Sep 2020 00:10:14

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-29T20:09:53', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'd643917c-7a20-493a-90f0-a97264a1fc37' User entered 'None (0)'	System	30 Sep 2020 00:10:14
	System	30 Sep 2020 00:10:14

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-29T20:09:56', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'd643917c-7a20-493a-90f0-a97264a1fc37' User entered 'None (0)'	System	30 Sep 2020 00:10:14
	System	30 Sep 2020 00:10:14

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-29T20:09:59', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'd643917c-7a20-493a-90f0-a97264a1fc37' User entered 'None (0)'	System	30 Sep 2020 00:10:14
	System	30 Sep 2020 00:10:14

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-29T20:10:02', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'd643917c-7a20-493a-90f0-a97264a1fc37' User entered 'None (0)'	System	30 Sep 2020 00:10:14
	System	30 Sep 2020 00:10:14



US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:47

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-29T20:10:07', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'd643917c-7a20-493a-90f0-a97264a1fc37'	System	30 Sep 2020 00:10:14
User entered 'No (N)'	System	30 Sep 2020 00:10:14

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-09-29T20:10:12', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'd643917c-7a20-493a-90f0-a97264a1fc37'	System	30 Sep 2020 00:10:14
User entered '29 Sep 2020 20:10'	System	30 Sep 2020 00:10:14

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	25 Sep 2020 19:19:50
User entered 'Day 6'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39



US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:47

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	25 Sep 2020 19:19:50
User entered 'Day 7'	System	25 Sep 2020 19:19:50



US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-10-02T00:14:58', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '254b0ed3-2088-4646-93a2-1c6579104d95'	System	02 Oct 2020 04:15:23
User entered 'None (0)'	System	02 Oct 2020 04:15:23

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-10-02T00:15:02', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '254b0ed3-2088-4646-93a2-1c6579104d95'	System	02 Oct 2020 04:15:23
User entered 'None (0)'	System	02 Oct 2020 04:15:23

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-10-02T00:15:07', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '254b0ed3-2088-4646-93a2-1c6579104d95' User entered 'None (0)'	System	02 Oct 2020 04:15:23
	System	02 Oct 2020 04:15:23

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-10-02T00:15:09', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '254b0ed3-2088-4646-93a2-1c6579104d95' User entered 'None (0)'	System	02 Oct 2020 04:15:23
	System	02 Oct 2020 04:15:23

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-10-02T00:15:12', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '254b0ed3-2088-4646-93a2-1c6579104d95' User entered 'None (0)'	System	02 Oct 2020 04:15:23
	System	02 Oct 2020 04:15:23

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-10-02T00:15:14', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '254b0ed3-2088-4646-93a2-1c6579104d95'	System	02 Oct 2020 04:15:23
User entered 'None (0)'	System	02 Oct 2020 04:15:23

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:47

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-10-02T00:15:19', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '254b0ed3-2088-4646-93a2-1c6579104d95'	System	02 Oct 2020 04:15:23
User entered 'No (N)'	System	02 Oct 2020 04:15:23

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-10-02T00:15:21', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '254b0ed3-2088-4646-93a2-1c6579104d95'	System	02 Oct 2020 04:15:23
User entered '02 Oct 2020 00:15'	System	02 Oct 2020 04:15:23



US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 19:19:50

US3822278

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:56:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 19:19:50

US3822278

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:00:05

US3822278

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:19
User entered '2 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:00:05

US3822278

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:00:05

US3822278

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:19
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:00:05

US3822278

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:00:09

US3822278

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered 'I'	System	05 Nov 2020 15:00:09



US3822278

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:00:20

US3822278

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:19
User entered '9 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:00:20

US3822278

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:00:20

US3822278

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:19
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:00:20

US3822278

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:00:27

US3822278

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered 'I'	System	05 Nov 2020 15:00:27

US3822278

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:19
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:39:54

US3822278

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:19
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:39:54



US3822278

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:19
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:39:54

US3822278

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:19
User entered 'nothing is entered in crio'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:39:54

US3822278

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:00:33

US3822278

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered 'I'	System	05 Nov 2020 15:00:33

US3822278

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:56:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:00:44

US3822278

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:56:47

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '27 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:00:44

US3822278

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:56:47

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:00:44

US3822278

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:56:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered 'VISIT3'	System	05 Nov 2020 15:00:44



US3822278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:01:14

US3822278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '27 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:01:14

US3822278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '15:15'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:01:14

US3822278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered '27 Oct 2020 15:15'	System	05 Nov 2020 15:01:14

US3822278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:01:14

US3822278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:01:14

US3822278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:01:14

US3822278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '67'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:01:14



US3822278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered 'bpm'	System	05 Nov 2020 15:01:14

US3822278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '16'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:01:14

US3822278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered 'breaths/min'	System	05 Nov 2020 15:01:14

US3822278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '122'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:01:14

US3822278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered 'mmHg'	System	05 Nov 2020 15:01:14

US3822278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '70'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:01:14

US3822278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered 'mmHg'	System	05 Nov 2020 15:01:14

US3822278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05



US3822278

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05

US3822278

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:56:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:01:17

US3822278

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:56:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:01:17

US3822278

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:02:04

US3822278

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '27 Oct 2020'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:02:04

US3822278

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered '15:25'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:02:04

US3822278

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered '27 Oct 2020 15:25'	System	05 Nov 2020 15:02:04

US3822278

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 20:51:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:02:54



US3822278

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered 'I'	System	05 Nov 2020 15:02:54

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07
Data entry locked.	System	26 Aug 2020 19:23:43
User entered 'Day 64'	System	26 Aug 2020 19:23:43

US3822278

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

US3822278

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

Fever (Temperature  $\geq$  100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07



US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07



US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07



US3822278

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

US3822278

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07
Data entry locked.	System	26 Aug 2020 19:23:43
User entered '26 Oct 2020 00:01'	System	26 Aug 2020 19:23:43

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07
Data entry locked.	System	26 Aug 2020 19:23:43
User entered '30 Oct 2020 23:59'	System	26 Aug 2020 19:23:43

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	26 Aug 2020 19:23:43
User entered 'Day 71'	System	26 Aug 2020 19:23:43

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-11-02T15:13:46', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'df815696-be37-4222-8682-c1786322561e' User entered 'No (N)'	System	02 Nov 2020 20:13:59
	System	02 Nov 2020 20:13:59

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-11-02T15:13:50', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'df815696-be37-4222-8682-c1786322561e' User entered 'No (N)'	System	02 Nov 2020 20:13:59
	System	02 Nov 2020 20:13:59



**US3822278**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-11-02T15:13:56', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'df815696-be37-4222-8682-c1786322561e' User entered '02 Nov 2020 15:13:56'	System	02 Nov 2020 20:13:59
	System	02 Nov 2020 20:13:59

**US3822278**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	26 Aug 2020 19:23:43
User entered '02 Nov 2020 00:01'	System	26 Aug 2020 19:23:43

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:45:39
Data entry locked.	System	26 Aug 2020 19:23:43
User entered '06 Nov 2020 23:59'	System	26 Aug 2020 19:23:43

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07
Data entry locked.	System	26 Aug 2020 19:23:43
User entered 'Day 78'	System	26 Aug 2020 19:23:43

US3822278

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07



US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

Fever (Temperature  $\geq$  100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07



US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07



US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

US3822278

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07
Data entry locked.	System	26 Aug 2020 19:23:43
User entered '09 Nov 2020 00:01'	System	26 Aug 2020 19:23:43

US3822278

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 18:27:07
Data entry locked.	System	26 Aug 2020 19:23:43
User entered '13 Nov 2020 23:59'	System	26 Aug 2020 19:23:43

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 18:27:07



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-11-30T16:33:50', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '55da4954-dbe8-443a-95fa-02a4ad8a61f8'	System	30 Nov 2020 21:34:27
User entered 'No (N)'	System	30 Nov 2020 21:34:27

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-11-30T16:33:54', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '55da4954-dbe8-443a-95fa-02a4ad8a61f8' User entered 'No (N)'	System	30 Nov 2020 21:34:27

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-11-30T16:34:23', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '55da4954-dbe8-443a-95fa-02a4ad8a61f8' User entered '30 Nov 2020 16:34:23'	System	30 Nov 2020 21:34:27
	System	30 Nov 2020 21:34:27

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 18:27:07



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-12-07T09:46:05', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '8da83d5d-940f-42e7-94d8-6e5a8438b75a' User entered 'Yes (Y)'	System	07 Dec 2020 14:46:11
	System	07 Dec 2020 14:46:11

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-12-07T09:45:27', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '8da83d5d-940f-42e7-94d8-6e5a8438b75a' User entered 'No (N)'	System	07 Dec 2020 14:46:11
	System	07 Dec 2020 14:46:11

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-12-07T09:45:33', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '8da83d5d-940f-42e7-94d8-6e5a8438b75a' User entered 'No (N)'	System	07 Dec 2020 14:46:11
	System	07 Dec 2020 14:46:11

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-12-07T09:45:48', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '8da83d5d-940f-42e7-94d8-6e5a8438b75a' User entered 'No (N)'	System	07 Dec 2020 14:46:11
	System	07 Dec 2020 14:46:11

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-12-07T09:46:09', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '8da83d5d-940f-42e7-94d8-6e5a8438b75a' User entered '07 Dec 2020 09:46:09'	System	07 Dec 2020 14:46:11
	System	07 Dec 2020 14:46:11

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 18:27:07



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 18:27:07

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-12-15T22:20:00', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'fb8ebccf-b159-46d4-8505-8966f29bc7c1' User entered 'Yes (Y)'	System	16 Dec 2020 03:20:35
	System	16 Dec 2020 03:20:35

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-12-15T22:20:06', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'fb8ebccf-b159-46d4-8505-8966f29bc7c1'	System	16 Dec 2020 03:20:35
User entered 'No (N)'	System	16 Dec 2020 03:20:35

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-12-15T22:20:13', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'fb8ebccf-b159-46d4-8505-8966f29bc7c1' User entered 'No (N)'	System	16 Dec 2020 03:20:35

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-12-15T22:20:21', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'fb8ebccf-b159-46d4-8505-8966f29bc7c1' User entered 'No (N)'	System	16 Dec 2020 03:20:35
	System	16 Dec 2020 03:20:35

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-12-15T22:20:29', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'fb8ebccf-b159-46d4-8505-8966f29bc7c1' User entered '15 Dec 2020 22:20:29'	System	16 Dec 2020 03:20:35
	System	16 Dec 2020 03:20:35

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 18:27:07



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 18:27:07

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-12-20T20:28:00', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'da3421dc-230d-4c95-9775-e2d7de2bcaf0' User entered 'No (N)'	System	21 Dec 2020 01:28:19
	System	21 Dec 2020 01:28:19

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-12-20T20:28:05', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'da3421dc-230d-4c95-9775-e2d7de2bcaf0' User entered 'No (N)'	System	21 Dec 2020 01:28:19
	System	21 Dec 2020 01:28:19

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-12-20T20:28:17', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'da3421dc-230d-4c95-9775-e2d7de2bcaf0' User entered '20 Dec 2020 20:28:17'	System	21 Dec 2020 01:28:19
	System	21 Dec 2020 01:28:19

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-12-25T01:45:17', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '30372708-7699-44aa-8df9-bd269bf8950b' User entered 'No (N)'	System	25 Dec 2020 06:45:28
	System	25 Dec 2020 06:45:28



US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-12-25T01:45:21', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '30372708-7699-44aa-8df9-bd269bf8950b' User entered 'No (N)'	System	25 Dec 2020 06:45:28
	System	25 Dec 2020 06:45:28

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2020-12-25T01:45:26', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '30372708-7699-44aa-8df9-bd269bf8950b' User entered '25 Dec 2020 01:45:26'	System	25 Dec 2020 06:45:28
	System	25 Dec 2020 06:45:28

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-01-05T13:32:58', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '50623f07-e61e-4445-817d-54abba1d72be' User entered 'No (N)'	System	05 Jan 2021 18:33:17
	System	05 Jan 2021 18:33:17

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-01-05T13:33:02', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '50623f07-e61e-4445-817d-54abba1d72be' User entered 'No (N)'	System	05 Jan 2021 18:33:17
	System	05 Jan 2021 18:33:17

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-01-05T13:33:10', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '50623f07-e61e-4445-817d-54abba1d72be' User entered '05 Jan 2021 13:33:10'	System	05 Jan 2021 18:33:17
	System	05 Jan 2021 18:33:17



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-01-09T17:38:25', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '512b4222-0d4d-4d05-a2c9-497e695bcfe9' User entered 'No (N)'	System	09 Jan 2021 22:38:39
	System	09 Jan 2021 22:38:39

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-01-09T17:38:30', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '512b4222-0d4d-4d05-a2c9-497e695bcfe9' User entered 'No (N)'	System	09 Jan 2021 22:38:39
	System	09 Jan 2021 22:38:39

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-01-09T17:38:35', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '512b4222-0d4d-4d05-a2c9-497e695bcfe9' User entered '09 Jan 2021 17:38:35'	System	09 Jan 2021 22:38:39
	System	09 Jan 2021 22:38:39

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 18:27:07



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-01-26T22:48:06', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '4fa48a0b-748e-4e78-9136-0a72b0b7e673' User entered 'No (N)'	System	27 Jan 2021 03:48:18
	System	27 Jan 2021 03:48:18

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-01-26T22:48:09', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '4fa48a0b-748e-4e78-9136-0a72b0b7e673'	System	27 Jan 2021 03:48:18
User entered 'No (N)'	System	27 Jan 2021 03:48:18

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-01-26T22:48:13', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '4fa48a0b-748e-4e78-9136-0a72b0b7e673' User entered '26 Jan 2021 22:48:13'	System	27 Jan 2021 03:48:18
	System	27 Jan 2021 03:48:18

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 18:27:07



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 18:27:07

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-01-29T15:25:08', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '90138ecf-dcfc-4d17-8110-c3764d4787fa' User entered 'No (N)'	System	29 Jan 2021 20:25:20
	System	29 Jan 2021 20:25:20

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-01-29T15:25:11', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '90138ecf-dcfc-4d17-8110-c3764d4787fa' User entered 'No (N)'	System	29 Jan 2021 20:25:20
	System	29 Jan 2021 20:25:20

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-01-29T15:25:17', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '90138ecf-dcfc-4d17-8110-c3764d4787fa' User entered '29 Jan 2021 15:25:17'	System	29 Jan 2021 20:25:20
	System	29 Jan 2021 20:25:20

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 18:27:07



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 18:27:07

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-02-15T22:14:36', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '24eec852-ec62-4e9a-8351-5b5b6b429f64' User entered 'No (N)'	System	16 Feb 2021 03:14:54

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-02-15T22:14:45', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '24eec852-ec62-4e9a-8351-5b5b6b429f64' User entered 'No (N)'	System	16 Feb 2021 03:14:54

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-02-15T22:14:53', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '24eec852-ec62-4e9a-8351-5b5b6b429f64' User entered '15 Feb 2021 22:14:53'	System	16 Feb 2021 03:14:54
	System	16 Feb 2021 03:14:54

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 18:27:07



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 18:27:07

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-02-19T14:40:49', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '83e4c3fc-a949-44e1-9eac-47af29172545'	System	19 Feb 2021 19:42:02
User entered 'Yes (Y)'	System	19 Feb 2021 19:42:02

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-02-19T14:40:43', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '83e4c3fc-a949-44e1-9eac-47af29172545'	System	19 Feb 2021 19:42:02
User entered 'Yes (Y)'	System	19 Feb 2021 19:42:02

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-02-19T14:41:11', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '83e4c3fc-a949-44e1-9eac-47af29172545'	System	19 Feb 2021 19:42:02
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Feb 2021 19:42:02

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-02-19T14:41:17', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '83e4c3fc-a949-44e1-9eac-47af29172545' User entered 'No (N)'	System	19 Feb 2021 19:42:02
	System	19 Feb 2021 19:42:02

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-02-19T14:41:27', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '83e4c3fc-a949-44e1-9eac-47af29172545'	System	19 Feb 2021 19:42:02
User entered 'Yes (Y)'	System	19 Feb 2021 19:42:02

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-02-19T14:41:30', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '83e4c3fc-a949-44e1-9eac-47af29172545'	System	19 Feb 2021 19:42:02
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Feb 2021 19:42:02

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-02-19T14:41:51', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '83e4c3fc-a949-44e1-9eac-47af29172545' User entered '19 Feb 2021 14:41:51'	System	19 Feb 2021 19:42:02
	System	19 Feb 2021 19:42:02



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-02-26T00:12:26-05:00', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '670c12a1-066f-409a-9ccd-61723146d41d' User entered 'Yes (Y)'	System	26 Feb 2021 05:13:11
	System	26 Feb 2021 05:13:11

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-02-26T00:12:32-05:00', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '670c12a1-066f-409a-9ccd-61723146d41d' User entered 'No (N)'	System	26 Feb 2021 05:13:11
	System	26 Feb 2021 05:13:11

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-02-26T00:12:52-05:00', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '670c12a1-066f-409a-9ccd-61723146d41d' User entered 'No (N)'	System	26 Feb 2021 05:13:11
	System	26 Feb 2021 05:13:11

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-02-26T00:13:03-05:00', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '670c12a1-066f-409a-9ccd-61723146d41d' User entered 'No (N)'	System	26 Feb 2021 05:13:11
	System	26 Feb 2021 05:13:11

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-02-26T00:13:08-05:00', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '670c12a1-066f-409a-9ccd-61723146d41d' User entered '26 Feb 2021 05:13:08'	System	26 Feb 2021 05:13:11
	System	26 Feb 2021 05:13:11



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 18:27:07

US3822278

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-03-08T13:12:07-05:00', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '3bdaff64-9406-4abb-90a4-452cae15b3fe' User entered 'No (N)'	System	08 Mar 2021 18:17:40
	System	08 Mar 2021 18:17:40

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-03-08T13:12:11-05:00', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '3bdaff64-9406-4abb-90a4-452cae15b3fe'	System	08 Mar 2021 18:17:40
User entered 'No (N)'	System	08 Mar 2021 18:17:40

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-03-08T13:12:16-05:00', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '3bdaff64-9406-4abb-90a4-452cae15b3fe' User entered '08 Mar 2021 13:12:16'	System	08 Mar 2021 18:17:40
	System	08 Mar 2021 18:17:40

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 18:27:07



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-03-16T22:12:24-04:00', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'e5038769-73d7-4218-8263-69a1a78a6dfc'	System	17 Mar 2021 02:12:43
User entered 'No (N)'	System	17 Mar 2021 02:12:43

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-03-16T22:12:29-04:00', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'e5038769-73d7-4218-8263-69a1a78a6dfc'	System	17 Mar 2021 02:12:43
User entered 'No (N)'	System	17 Mar 2021 02:12:43

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-03-16T22:12:40-04:00', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'e5038769-73d7-4218-8263-69a1a78a6dfc' User entered '16 Mar 2021 22:12:40'	System	17 Mar 2021 02:12:43
	System	17 Mar 2021 02:12:43

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 18:27:07

US3822278

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-03-19T13:17:04-04:00', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'e304516f-6e77-4d7e-93d6-422757653113'	System	19 Mar 2021 17:17:16
User entered 'No (N)'	System	19 Mar 2021 17:17:16



US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-03-19T13:17:08-04:00', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'e304516f-6e77-4d7e-93d6-422757653113'	System	19 Mar 2021 17:17:16
User entered 'No (N)'	System	19 Mar 2021 17:17:16

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-03-19T13:17:13-04:00', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'e304516f-6e77-4d7e-93d6-422757653113'	System	19 Mar 2021 17:17:16
User entered '19 Mar 2021 13:17:13'	System	19 Mar 2021 17:17:16

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 18:27:07

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-03-29T20:58:14-04:00', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'dfce7799-a4aa-4bdd-a97a-2d06c3991407'	System	30 Mar 2021 00:58:39
User entered 'No (N)'	System	30 Mar 2021 00:58:39

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-03-29T20:58:21-04:00', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'dfce7799-a4aa-4bdd-a97a-2d06c3991407'	System	30 Mar 2021 00:58:39
User entered 'No (N)'	System	30 Mar 2021 00:58:39

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-03-29T20:58:31-04:00', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'dfce7799-a4aa-4bdd-a97a-2d06c3991407'	System	30 Mar 2021 00:58:39
User entered '29 Mar 2021 20:58:31'	System	30 Mar 2021 00:58:39



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-04-04T21:00:03-04:00', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '9d6eb80a-92db-4cba-be1c-9957472afc0e' User entered 'No (N)'	System	05 Apr 2021 01:00:24
	System	05 Apr 2021 01:00:24

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-04-04T21:00:08-04:00', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '9d6eb80a-92db-4cba-be1c-9957472afc0e' User entered 'No (N)'	System	05 Apr 2021 01:00:24
	System	05 Apr 2021 01:00:24

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-04-04T21:00:19-04:00', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '9d6eb80a-92db-4cba-be1c-9957472afc0e' User entered '04 Apr 2021 21:00:19'	System	05 Apr 2021 01:00:24
	System	05 Apr 2021 01:00:24

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 18:27:07



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-04-13T13:27:55-04:00', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '65ac76e2-af21-4e92-bf10-d66496a30c2d' User entered 'No (N)'	System	13 Apr 2021 17:28:09
	System	13 Apr 2021 17:28:09

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-04-13T13:28:00-04:00', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '65ac76e2-af21-4e92-bf10-d66496a30c2d' User entered 'No (N)'	System	13 Apr 2021 17:28:09

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-04-13T13:28:06-04:00', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '65ac76e2-af21-4e92-bf10-d66496a30c2d' User entered '13 Apr 2021 13:28:06'	System	13 Apr 2021 17:28:09
	System	13 Apr 2021 17:28:09

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 18:27:07



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-04-23T15:09:29-04:00', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'cbd85445-c133-4b46-abac-8045ef24dd7a' User entered 'No (N)'	System	23 Apr 2021 19:10:08
	System	23 Apr 2021 19:10:08

US3822278

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:56:47

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-04-23T15:09:57-04:00', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'cbd85445-c133-4b46-abac-8045ef24dd7a' User entered 'No (N)'	System	23 Apr 2021 19:10:08
	System	23 Apr 2021 19:10:08

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-04-23T15:10:06-04:00', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'cbd85445-c133-4b46-abac-8045ef24dd7a' User entered '23 Apr 2021 15:10:06'	System	23 Apr 2021 19:10:08
	System	23 Apr 2021 19:10:08

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 18:27:07



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-05-03T18:06:32-04:00', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'c8eae003-1d88-42bd-8ecc-37f45466f2e1'	System	03 May 2021 22:12:51
User entered 'No (N)'	System	03 May 2021 22:12:51

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-05-03T18:06:38-04:00', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'c8eae003-1d88-42bd-8ecc-37f45466f2e1'	System	03 May 2021 22:12:51
User entered 'No (N)'	System	03 May 2021 22:12:51

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-05-03T18:06:47-04:00', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: 'c8eae003-1d88-42bd-8ecc-37f45466f2e1' User entered '03 May 2021 18:06:47'	System	03 May 2021 22:12:51
	System	03 May 2021 22:12:51

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 18:27:07



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 18:27:07



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 18:27:07



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 18:27:07



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 18:27:07



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 18:27:07



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 18:27:07



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 18:27:07



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 18:27:07



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 18:27:07



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 18:27:07



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 18:27:07



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 18:27:07



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 18:27:07



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 18:27:07



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 18:27:07



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 18:27:07



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 18:27:07



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 18:27:07



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 18:27:07



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 18:27:07



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 18:27:07



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 18:27:07



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 18:27:07



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 18:27:07



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 18:27:07



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 18:27:07



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 18:27:07



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 18:27:07



**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '28 Oct 2022 00:01'	System	19 Nov 2020 18:27:07

**US3822278**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:56:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 18:27:07
Amendment Manager: User entered '01 Nov 2022 23:59'	System	19 Nov 2020 18:27:07

US3822278

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:56:47**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-03-08T13:12:36-05:00', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '268a8476-c19e-45dd-860d-db4445218e01'	System	08 Mar 2021 18:18:00
User entered 'No (N)'	System	08 Mar 2021 18:18:00



US3822278

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:56:47

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:25:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2F1D5736-B082-4FEC-B82A-B4EABE3626F7)', Time: '2021-03-08T13:12:44-05:00', User OID: 'PatientReportedOutcome (US3822278)', ODM File OID: '268a8476-c19e-45dd-860d-db4445218e01'	System	08 Mar 2021 18:18:00
User entered '08 Mar 2021 13:12:44'	System	08 Mar 2021 18:18:00

US3822278

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:21:17
User entered 'Yes (Y)'	Krishna Shah (b) (4)	09 Dec 2020 23:07:59

US3822278

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:21:17
User entered '20 Nov 2020'	Krishna Shah (b) (4)	09 Dec 2020 23:07:59

US3822278

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:21:17
User entered 'Contact Made (CONTACT MADE)'	Krishna Shah (b) (4)	09 Dec 2020 23:07:59

US3822278

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:21:17
User entered empty.	(b) (4) Krishna Shah (b) (4) (b) (4)	09 Dec 2020 23:07:59

US3822278

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:21:17
User entered 'Yes (Y)'	Krishna Shah (b) (4)	09 Dec 2020 23:08:10

US3822278

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:17:05
User entered 'I'	System	09 Dec 2020 23:08:10

US3822278

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:38:05
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	12 Jan 2021 00:35:05



US3822278

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:38:05
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered '21 Dec 2020'	Kelly Woodell (b) (4)	12 Jan 2021 00:35:05

US3822278

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:38:05
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered 'Contact Made (CONTACT MADE)'	Kelly Woodell (b) (4)	12 Jan 2021 00:35:05

US3822278

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:38:05
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered empty.	Kelly Woodell (b) (4)	12 Jan 2021 00:35:05

US3822278

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:38:05
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	12 Jan 2021 00:35:09

US3822278

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:38:05
User entered 'I'	System	12 Jan 2021 00:35:09

US3822278

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:38:05
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	03 Feb 2021 22:18:44

US3822278

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:38:05
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered '22 Jan 2021'	Kelly Woodell (b) (4)	03 Feb 2021 22:18:44

US3822278

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:38:05
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered 'Contact Made (CONTACT MADE)'	Kelly Woodell (b) (4)	03 Feb 2021 22:18:44



US3822278

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:38:05
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered empty.	Kelly Woodell (b) (4)	03 Feb 2021 22:18:44

US3822278

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:38:05
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	03 Feb 2021 22:18:47

US3822278

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:38:05
User entered 'I'	System	03 Feb 2021 22:18:47

US3822278

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:38:05
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:19:27

US3822278

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:38:05
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:19:27

US3822278

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:38:05
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:19:27

US3822278

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:38:05
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:19:27

US3822278

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:02:41
User closed query 'Per GCL Lab Recon: Immuno : Sample dated "19 MAR 2021" is reported under Visit 4 D 209 in PPD GCL, however the same is missing in EDC. Please update the missing sample details in the Visit 4 D 209 Immunogenicity assessment form in EDC. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 13:51:52
Query 'Per GCL Lab Recon: Immuno : Sample dated "19 MAR 2021" is reported under Visit 4 D 209 in PPD GCL, however the same is missing in EDC. Please update the missing sample details in the Visit 4 D 209 Immunogenicity assessment form in EDC. Thank you.' answered with 'V4 data has been entered' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 15:36:42
User opened query 'Per GCL Lab Recon: Immuno : Sample dated "19 MAR 2021" is reported under Visit 4 D 209 in PPD GCL, however the same is missing in EDC. Please update the missing sample details in the Visit 4 D 209 Immunogenicity assessment form in EDC. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 20:36:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Feb 2021 18:19:32



US3822278

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:02:41
User entered 'I'	System	22 Feb 2021 18:19:32

US3822278

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:56:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:10:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:37:00

US3822278

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:56:47

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:10:06
User entered '19 Mar 2021'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:37:00

US3822278

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:56:47

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:10:06
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:37:00

US3822278

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:56:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered 'VISIT4'	System	06 Apr 2021 15:37:00

US3822278

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:10:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:37:04

US3822278

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:10:06
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:37:04

US3822278

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:10:06
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:37:04



US3822278

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered empty.	System	06 Apr 2021 15:37:04

US3822278

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:10:06
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:37:04

US3822278

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:10:06
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:37:04

US3822278

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:10:06
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:37:04

US3822278

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:10:06
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:37:04

US3822278

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered empty.	System	06 Apr 2021 15:37:04

US3822278

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:10:06
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:37:04

US3822278

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered empty.	System	06 Apr 2021 15:37:04



US3822278

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:10:06
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:37:04

US3822278

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered empty.	System	06 Apr 2021 15:37:04

US3822278

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:10:06
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:37:04

US3822278

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered empty.	System	06 Apr 2021 15:37:04

US3822278

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10

US3822278

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:56:47

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10

US3822278

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:56:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:10:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:37:18

US3822278

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:56:47

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:10:06
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:37:18



US3822278

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:10:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:37:30

US3822278

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:47

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:10:06
User entered '19 Mar 2021'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:37:30

US3822278

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:10:06
User entered '14:27'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:37:30

US3822278

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered '19 Mar 2021 14:27'	System	06 Apr 2021 15:37:30

US3822278

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:10:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:37:35

US3822278

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:34:10
User entered 'I'	System	06 Apr 2021 15:37:35

US3822278

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	28 Apr 2021 06:23:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 20:19:26

US3822278

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	28 Apr 2021 06:23:00
User entered '23 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 20:19:26



US3822278

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	28 Apr 2021 06:23:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 20:19:26

US3822278

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:56:47

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	28 Apr 2021 06:23:00
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 20:19:26

US3822278

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:56:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	28 Apr 2021 06:23:00
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Apr 2021 20:19:31

**US3822278**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:56:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Apr 2021 20:19:31

US3822278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:56:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:32:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	19 Jan 2021 16:39:18

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:56:47

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:32:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered '13 Jan 2021'	Kelly Woodell (b) (4)	19 Jan 2021 16:39:18

US3822278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:56:47

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:32:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered 'Clinic (Clinic)'	Kelly Woodell (b) (4)	19 Jan 2021 16:39:18

US3822278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:56:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:32:56
User entered 'UNBLND_DECIDE'	System	19 Jan 2021 16:39:18



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:56:47

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:32:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered '13 Jan 2021'	Kelly Woodell (b) (4)	19 Jan 2021 16:39:30

US3822278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:56:47

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:32:56
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:10:06
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:21:21
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:41:03

US3822278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:56:47

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:32:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	19 Jan 2021 16:39:30

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:56:47

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:32:56
User closed query 'Per CDM: Per Sponsor review: 'Under what version of the Protocol was the participant unblinded?' is blank - Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 15:52:47
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:10:06
Query 'Per CDM: Per Sponsor review: 'Under what version of the Protocol was the participant unblinded?' is blank - Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. Thank you. ' answered with 'Subject was unblinded under A6' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 13:21:48
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	09 Apr 2021 13:21:21
User opened query 'Per CDM: Per Sponsor review: 'Under what version of the Protocol was the participant unblinded?' is blank - Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. Thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 13:56:42
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:41:03

US3822278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:56:47

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:32:56
User signature succeeded.	Christina Kennelly (b) (4)	23 Apr 2021 14:44:35
User closed query 'Per CDM RQ: Response noted. However, this field is for the date of unblinding in IRT. Please reconcile. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Apr 2021 11:15:12
User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	(b) (4), (b) (6)	20 Apr 2021 13:52:46
Query 'Per CDM RQ: Response noted. However, this field is for the date of unblinding in IRT. Please reconcile. Thank you' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 17:11:29
Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered with 'Patient unblinded in IRT prior to coming into clinic to actually be unblinded' (Site from System).	(b) (4), (b) (6)	16 Apr 2021 17:11:18
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	16 Apr 2021 17:11:08
Signature has been broken.	(b) (4), (b) (6)	16 Apr 2021 17:11:08
User entered '12 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 17:11:08
User opened query 'Per CDM RQ: Response noted. However, this field is for the date of unblinding in IRT. Please reconcile. Thank you' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 15:52:49
User closed query 'Per IRT, subject was unblinded on 12JAN2021. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 15:52:49
Query 'Per IRT, subject was unblinded on 12JAN2021. Please review and reconcile.' answered with 'Subject was unblinded in IRT on 12JAN2021, however, subject was unblinded in clinic on 13JAN2021' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 13:22:24
User opened query 'Per IRT, subject was unblinded on 12JAN2021. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 16:16:24
User signature succeeded.	Christina Kennelly (b) (4) (b) (4)	02 Apr 2021 21:58:04

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:56:47

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Jan 2021'	Kelly Woodell (b) (4) (b) (4)	19 Jan 2021 16:39:30

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:56:47

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:32:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered 'mRNA-1273 (mRNA-1273)'	Kelly Woodell (b) (4)	19 Jan 2021 16:39:30

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:56:47

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:32:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 13:01:47
User entered 'mRNA-1273 (mRNA-1273)'	Kelly Woodell (b) (4)	19 Jan 2021 16:39:30
	(b) (4)	



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:56:47

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:32:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 13:01:47
User entered 'mRNA-1273 (mRNA-1273)'	Kelly Woodell (b) (4)	19 Jan 2021 16:39:30
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:56:47

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:32:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered 'No (N)'	Kelly Woodell (b) (4)	19 Jan 2021 16:39:30

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:56:47

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:32:56
User entered empty.	System	19 Jan 2021 16:39:30

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:56:47

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:32:56
User entered empty.	System	19 Jan 2021 16:39:30

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:32:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	19 Jan 2021 16:39:41

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:32:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered '13 Jan 2021'	Kelly Woodell (b) (4)	19 Jan 2021 16:39:41

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:32:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered '15:58'	Kelly Woodell (b) (4)	19 Jan 2021 16:39:41

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:56:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:32:56
User entered '13 Jan 2021 15:58'	System	19 Jan 2021 16:39:41



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:56:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:32:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	19 Jan 2021 16:39:51

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:56:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:32:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered '13 Jan 2021'	Kelly Woodell (b) (4)	19 Jan 2021 16:39:51

US3822278

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:56:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:32:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered '16:09'	Kelly Woodell (b) (4)	19 Jan 2021 16:39:51

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**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:56:47**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 23:32:56
User entered '13 Jan 2021 16:09'	System	19 Jan 2021 16:39:51

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:56:47

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:13:59
User closed query 'Per DM CLR: Per Day 180 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 11:24:41
Query 'Per DM CLR: Per Day 180 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'New medication has been added to Conmeds' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 12:47:37
User opened query 'Per DM CLR: Per Day 180 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 09:55:23
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
User closed query 'Please complete Concomitant Procedures Summary Page.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 13:30:24
Query 'Please complete Concomitant Procedures Summary Page.' answered with 'Completed' (Site from CRA).	Kelly Woodell (b) (4)	23 Nov 2020 23:34:52
User opened query 'Please complete Concomitant Procedures Summary Page.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 19:06:33

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:56:47

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:32:23
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 17:43:43

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:56:47

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
User closed query 'Please add/reconcile unsolicited AE of Fatigue as noted in CRIO if applicable.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 03:21:12
Query 'Please add/reconcile unsolicited AE of Fatigue as noted in CRIO if applicable.' answered with 'added' (Site from CRA).	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 22:09:48
User opened query 'Please add/reconcile unsolicited AE of Fatigue as noted in CRIO if applicable.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 20:58:08
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:30:03
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:20
User entered 'USA-US126-2020-mRNA-1273-P301000003'	System	29 Sep 2020 13:36:15
User entered 'New'	(b) (4), (b) (6)	29 Sep 2020 13:36:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:56:47

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 20:55:02
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Electrolyte and fluid balance conditions, HLT: Total fluid volume decreased, PT: Dehydration, LLT: Dehydration - version MedDRA\23.0.	Coder Import (b) (4)	14 Oct 2020 14:58:32
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Oct 2020 14:58:32
Data point term sent to Coder	System	14 Oct 2020 14:57:10
DataPoint Un-verified.	(b) (4), (b) (6)	14 Oct 2020 14:56:12
Coding entries removed.	(b) (4), (b) (6)	14 Oct 2020 14:56:12
User entered 'Dehydration' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Oct 2020 14:56:12
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:31:23
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Fall, LLT: Fall - version MedDRA\23.0.	Coder Import (b) (4)	28 Sep 2020 17:46:43
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	28 Sep 2020 17:46:43
Data point term sent to Coder	System	28 Sep 2020 17:45:57
User entered 'Fall'	Krishna Shah (b) (4)	28 Sep 2020 17:45:45
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:56:47

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 13:37:40
User closed query 'Per sponsor review, SAE resulted in inpatient hospitalization. Please update field accordingly.' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 05:12:49
Query 'Per sponsor review, SAE resulted in inpatient hospitalization. Please update field accordingly.' answered with 'updated ' (Site from DM).	Krishna Shah (b) (4)	30 Dec 2020 16:56:01
DataPoint Un-verified.	(b) (4)	
	Krishna Shah (b) (4)	30 Dec 2020 16:55:55
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Krishna Shah (b) (4)	30 Dec 2020 16:55:55
User opened query 'Per sponsor review, SAE resulted in inpatient hospitalization. Please update field accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 15:07:55
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:31:23
User entered 'No (N)'	Krishna Shah (b) (4)	28 Sep 2020 17:45:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:56:47

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:31:23
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 17:45:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:56:47

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:31:23
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 17:45:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:56:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:31:23
User entered '26 Sep 2020'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 17:45:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:56:47

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 20:05:37
User closed query 'Per CRIO Start Time is 15:00. Please reconcile and update if applicable.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:05:35
Query 'Per CRIO Start Time is 15:00. Please reconcile and update if applicable.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:05:15
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 15:05:08
User entered '15:00' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 15:05:08
User opened query 'Per CRIO Start Time is 15:00. Please reconcile and update if applicable.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 20:54:44
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:31:23
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 12:46:18
Query 'Data is required. Please provide.' answered with 'exact time unknown. Per patient it was late Saturday night. ' (Site from System).	Krishna Shah (b) (4)	28 Sep 2020 17:46:37
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	28 Sep 2020 17:45:45
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 17:45:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:56:47

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 15:00'	System	05 Nov 2020 15:05:08
User entered empty.	System	28 Sep 2020 17:45:45

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:56:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 20:55:02
DataPoint Un-verified.	(b) (4), (b) (6)	14 Oct 2020 14:56:12
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	14 Oct 2020 14:56:12
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:31:23
User entered 'Yes (Y)'	Krishna Shah (b) (4)	28 Sep 2020 17:45:45
	(b) (4)	

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 20:55:02
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)	16 Oct 2020 12:51:14
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 'End date added' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 12:31:31
DataPoint Un-verified.	(b) (4), (b) (6)	14 Oct 2020 14:56:12
User entered '28 Sep 2020' reason for change: Per Query Resolution	(b) (4), (b) (6)	14 Oct 2020 14:56:12
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:31:23
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)	08 Oct 2020 17:26:25
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 17:45:45
	(b) (4)	



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End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 15:29:01
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	05 Feb 2021 18:25:22
User entered '00:00' reason for change: Per Query Resolution	Christina Kennelly (b) (4)	05 Feb 2021 18:25:22
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	05 Feb 2021 18:24:21
DataPoint Un-verified.	Christina Kennelly (b) (4)	05 Feb 2021 18:24:21
	(b) (4)	
User entered '24:00' (non-conformant).	Christina Kennelly (b) (4)	05 Feb 2021 18:24:21
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 09:19:03
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:55:02
	(b) (4)	
Query 'Data is required. Please provide.' answered with 'end time is unknown' (Site from System).	Kelly Woodell (b) (4)	04 Nov 2020 16:39:25
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Nov 2020 16:39:03
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Nov 2020 16:39:03
User entered empty; reason for change Per Query Resolution	Kelly Woodell (b) (4)	04 Nov 2020 16:39:03
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	15 Oct 2020 12:28:55
User closed query 'Data is required. Please provide.' (Site from System).	System	15 Oct 2020 12:28:55
DataPoint Un-verified.	(b) (4), (b) (6)	15 Oct 2020 12:28:55
	(b) (4), (b) (6)	
User entered 'NK:NK' (non-conformant).	(b) (4), (b) (6)	15 Oct 2020 12:28:55
	(b) (4), (b) (6)	
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Oct 2020 14:56:12
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:31:23
	(b) (4)	
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 17:45:45
	(b) (4)	

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 00:00'	System	05 Feb 2021 18:25:22
User entered '28 Sep 2020 24:00' (non-conformant).	System	05 Feb 2021 18:24:21
User entered empty.	System	04 Nov 2020 16:39:03
User entered '28 Sep 2020 NK:NK' (non-conformant).	System	15 Oct 2020 12:28:55
User entered empty.	System	28 Sep 2020 17:45:45

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:31:23
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 17:45:45

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:31:23
User entered 'Yes (Y)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 17:45:45

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:31:23
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 17:45:45

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Folder: Adverse Events

Form: Adverse Events (1)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:31:23
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 17:45:45

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Folder: Adverse Events

Form: Adverse Events (1)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4)	15 Oct 2020 12:28:55
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	15 Oct 2020 12:28:55
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:31:23
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	28 Sep 2020 17:45:45
User entered 'I'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 17:45:45

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Form: Adverse Events (1)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:31:23
User entered '26 Sep 2020'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 17:45:45



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Form: Adverse Events (1)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 20:55:02
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 12:51:19
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'Discharge date added' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 12:31:28
DataPoint Un-verified.	(b) (4), (b) (6)	15 Oct 2020 12:28:55
User entered '28 Sep 2020' reason for change: New Information	(b) (4), (b) (6)	15 Oct 2020 12:28:55
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:31:23
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 17:26:48
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 17:45:45
	(b) (4)	

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:31:23
User entered 'No (N)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 17:45:45

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:31:23
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 17:45:45

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Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:31:23
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 17:45:45

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Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:31:23
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 17:45:45

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:31:23
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 17:45:45

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:31:23
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 13:35:58
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 20:50:40
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 20:49:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Sep 2020 20:49:03
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 20:49:03
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	28 Sep 2020 19:54:50
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 17:45:45
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 17:45:45
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:31:23
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 20:49:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Sep 2020 20:49:03
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 20:49:03
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 17:45:45
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 17:45:45
	(b) (4)	



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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
Query 'PV Query: As the last dose of mRNA-1273 was given on 25 Sep 2020 (prior to event onset - Fatigue), please update the action taken with mRNA-1273 for the event of Fatigue from none to not applicable. Please leave query open until information is received.' canceled (Site from Safety).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 19:54:41
User opened query 'PV Query: As the last dose of mRNA-1273 was given on 25 Sep 2020 (prior to event onset - Fatigue), please update the action taken with mRNA-1273 for the event of Fatigue from none to not applicable. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 19:54:33
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:55:02
User closed query 'PV Query: As the last dose of study drug was given on 25 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 12:51:24
Query 'PV Query: As the last dose of study drug was given on 25 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'Corrected' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 12:31:36
DataPoint Un-verified.	(b) (4), (b) (6)	15 Oct 2020 12:28:55
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 12:28:55
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:31:23
User opened query 'PV Query: As the last dose of study drug was given on 25 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 17:27:24
User entered 'None (NONE)'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 17:45:45

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None

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
Signature has been broken.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 14:31:34
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:05:10
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 12:43:35
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 12:43:35
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:31:23
User entered '1'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 17:45:45

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 21:05:12
User closed query 'Per CRIO source, conmed of Saline with Magnesium was used to treat AE/SAE. Please reconcile and update if applicable.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 21:05:08
Query 'Per CRIO source, conmed of Saline with Magnesium was used to treat AE/SAE. Please reconcile and update if applicable.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 12:43:41
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 12:43:35
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 12:43:35
User opened query 'Per CRIO source, conmed of Saline with Magnesium was used to treat AE/SAE. Please reconcile and update if applicable.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 19:18:54
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:31:23
User entered '0'	Krishna Shah (b) (4)	28 Sep 2020 17:45:45
	(b) (4)	

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:31:23
User entered '0'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 17:45:45

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 20:55:02
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.' canceled (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 15:09:39
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 12:32:31
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 12:32:31
DataPoint Un-verified.	(b) (4), (b) (6)	15 Oct 2020 12:32:31
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	15 Oct 2020 12:32:31
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:31:23
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)	08 Oct 2020 17:26:37
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 17:45:45
User entered empty.	Krishna Shah (b) (4)	28 Sep 2020 17:45:45
	(b) (4)	

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:31:23
User entered empty.	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 17:45:45

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
User closed query 'Per DM CLR - RQ: Site's response noted. However, please keep this query open until information is available. SAE Narrative = LUMBAR PUNCTURE. 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) (4), (b) (6)	21 Dec 2020 08:47:49
User closed query 'Per DM CLR: SAE Narrative = PATIENT HAD BAD GAIT AND FELL. However, please review and verify if BAD GAIT and FALL should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 04:25:18
Query 'Per DM CLR - RQ: Site's response noted. However, please keep this query open until information is available. SAE Narrative = LUMBAR PUNCTURE. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'LP added to conmed procedures' (Site from DM).	Krishna Shah (b) (4) (b) (4)	17 Dec 2020 22:13:03
Query 'Per DM CLR: SAE Narrative = PATIENT HAD BAD GAIT AND FELL. However, please review and verify if BAD GAIT and FALL should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'This is a narrative of why the patient had an AE of dehydration. I don't think this should be seperated into 2 terms. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 13:09:32
User opened query 'Per DM CLR - RQ: Site's response noted. However, please keep this query open until information is available. SAE Narrative = LUMBAR PUNCTURE. 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)	14 Dec 2020 06:07:23

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = PATIENT HAD BAD GAIT AND FELL. However, please review and verify if BAD GAIT and FALL should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 06:06:47
User closed query 'PV Query: Was there any treatment provided in a addition to the IV saline with magnesium? If yes, please update the narrative and/or concomitant medication eCRFs as applicable. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 14:48:00
User closed query 'PV Query: What was the etiology of dehydration (i.e poor oral intake, diarrhea, etc) Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 14:47:56
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 14:47:51
User closed query 'PV Query: It was reported the subject fell due to bad gait. What was the cause of the bad gait (i.e. underlying condition, problems with the legs and feet, accident) Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 14:47:48
User closed query 'PV Query: Please clarify if the subject sustained any injuries due to the fall. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 14:47:43
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. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 14:47:40
User closed query 'PV Query: Please provide indication and date of the lumbar puncture. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 14:47:36



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:56:47

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 14:47:33
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 14:47:29
Query 'PV Query: What was the etiology of dehydration (i.e poor oral intake, diarrhea, etc) Please leave query open until information is received.' answered with 'Per medical records, it seems that a large volume was taken during lumbar puncture which led to dehydration. ' (Site from Safety).	Krishna Shah (b) (4)	23 Nov 2020 21:18:37
Query 'PV Query: Was there any treatment provided in a addition to the IV saline with magnesium? If yes, please update the narrative and/or concomitant medication eCRFs as applicable. Please leave query open until information is received.' answered with 'No other medications were given--see discharge summary. ' (Site from Safety).	Krishna Shah (b) (4)	23 Nov 2020 21:16:56
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. Please leave query open until information is received.' answered with 'CBC, CMP, CPK, telemetry and CT of head were done. See discharge notes for results. ' (Site from Safety).	Krishna Shah (b) (4)	23 Nov 2020 21:15:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:56:47

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Discharge summary has been sent to the email above. ' (Site from Safety).	Krishna Shah (b) (4)	23 Nov 2020 21:14:48
Query 'PV Query: Please clarify if the subject sustained any injuries due to the fall. Please leave query open until information is received.' answered with 'There were no injuries identified due to the fall per medical records. ' (Site from Safety).	Krishna Shah (b) (4)	23 Nov 2020 21:14:33
Query 'PV Query: Please provide indication and date of the lumbar puncture. Please leave query open until information is received.' answered with 'Lumbar puncture was on 24Sep20 due to possible issues with her cardiac health see discharge summary sent. ' (Site from Safety).	Krishna Shah (b) (4)	23 Nov 2020 21:13:57
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is received.' answered with 'Labs and discharge summary sent to Safety_moderna email. ' (Site from Safety).	Krishna Shah (b) (4)	23 Nov 2020 21:10:44
Query 'PV Query: It was reported the subject fell due to bad gait. What was the cause of the bad gait (i.e. underlying condition, problems with the legs and feet, accident) Please leave query open until information is received.' answered with 'Cause of the bad gait was due to receiving the lumbar puncture (24Sep20) the day before second vaccination (25Sep20). ' (Site from Safety).	Krishna Shah (b) (4)	23 Nov 2020 20:02:12
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. Please leave query open until information is received.' answered with 'No Covid-19 testing was done at the hospital. ' (Site from Safety).	Krishna Shah (b) (4)	23 Nov 2020 20:01:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:56:47

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Was there any treatment provided in a addition to the IV saline with magnesium? If yes, please update the narrative and/or concomitant medication eCRFs as applicable. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 19:54:59
User opened query 'PV Query: What was the etiology of dehydration (i.e poor oral intake, diarrhea, etc) Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 19:54:20
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 19:54:12
User opened query 'PV Query: It was reported the subject fell due to bad gait. What was the cause of the bad gait (i.e. underlying condition, problems with the legs and feet, accident) Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 19:54:04
User opened query 'PV Query: Please clarify if the subject sustained any injuries due to the fall. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 19:52:58
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. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 19:52:50
User opened query 'PV Query: Please provide indication and date of the lumbar puncture. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 19:52:42

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Folder: Adverse Events

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Generated On: 10 Jun 2021 09:56:47

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 19:52:32
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 19:52:24
User closed query 'Per DM CLR: SAE Narrative indicates subject had a Lumbar Puncture. However, there is no corresponding Concomitant Procedure record to match this information. Please review and update to record the procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 09:24:04
User closed query 'PV Query: What was the etiology of dehydration (i.e poor oral intake, diarrhea, etc)' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 13:35:59
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 13:35:45
User closed query 'PV Query: It was reported the subject fell due to bad gait. What was the cause of the bad gait (i.e. underlying condition, problems with the legs and feet, accident)' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 13:35:42
User closed query 'PV Query: Please clarify if the subject sustained any injuries due to the fall.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 13:35:40
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)	05 Nov 2020 13:35:36

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide indication and date for the lumbar puncture.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 13:35:34
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 13:35:30
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 13:35:28
Query 'PV Query: It was reported the subject fell due to bad gait. What was the cause of the bad gait (i.e. underlying condition, problems with the legs and feet, accident)' answered with 'Unknown. Will be added once received.' (Site from Safety).	Kelly Woodell (b) (4)	04 Nov 2020 16:46:29
Query 'PV Query: What was the etiology of dehydration (i.e poor oral intake, diarrhea, etc)' answered with 'Unknown. Will be added once received.' (Site from Safety).	Kelly Woodell (b) (4)	04 Nov 2020 16:46:22
Query 'Per DM CLR: SAE Narrative indicates subject had a Lumbar Puncture. However, there is no corresponding Concomitant Procedure record to match this information. Please review and update to record the procedure as appropriate. Otherwise, clarify.' answered with 'Unknown. Will be added once received.' (Site from DM).	Kelly Woodell (b) (4)	04 Nov 2020 16:46:18
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Will send once received' (Site from Safety).	Kelly Woodell (b) (4)	04 Nov 2020 16:46:12
Query 'PV Query: Please clarify if the subject sustained any injuries due to the fall.' answered with 'Unknown. Will be added once received.' (Site from Safety).	Kelly Woodell (b) (4)	04 Nov 2020 16:45:55

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
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 'Unknown. Will be added once received.' (Site from Safety).	Kelly Woodell (b) (4)	04 Nov 2020 16:45:49
Query 'PV Query: Please provide indication and date for the lumbar puncture.' answered with 'Unknown. Will be added once received.' (Site from Safety).	Kelly Woodell (b) (4)	04 Nov 2020 16:45:41
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Unknown. Will be added once received.' (Site from Safety).	Kelly Woodell (b) (4)	04 Nov 2020 16:45:38
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Unknown. Will be added once received.' (Site from Safety).	Kelly Woodell (b) (4)	04 Nov 2020 16:45:35
User opened query 'PV Query: What was the etiology of dehydration (i.e poor oral intake, diarrhea, etc)' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 15:08:21
User opened query 'Per DM CLR: SAE Narrative indicates subject had a Lumbar Puncture. However, there is no corresponding Concomitant Procedure record to match this information. Please review and update to record the procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 02:00:16
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:31:23
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 17:27:48

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: It was reported the subject fell due to bad gait. What was the cause of the bad gait (i.e. underlying condition, problems with the legs and feet, accident)' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 17:27:42
User opened query 'PV Query: Please clarify if the subject sustained any injuries due to the fall.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 17:27:33
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)	08 Oct 2020 17:27:11
User opened query 'PV Query: Please provide indication and date for the lumbar puncture.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 17:27:04
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 17:26:57
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	08 Oct 2020 17:26:09
User entered 'Patient had bad gait and fell after a lumbar puncture.'	Krishna Shah (b) (4) (b) (4)	28 Sep 2020 17:45:45

**US3822278**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:56:47**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Sep 2020 17:45:45



**US3822278**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:56:47**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Dec 2020 16:55:55
User entered '0'	System	28 Sep 2020 17:45:45

**US3822278**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:56:47**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Sep 2020 17:45:45

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:47

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:59
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:57:57
User entered 'USA-US126-2020-mRNA-1273-P301000009'	System	24 Nov 2020 19:08:16
Un-reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:16
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 19:08:16
User entered 'New' reason for change: Obvious Correction	(b) (4), (b) (6)	24 Nov 2020 19:08:16
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:06:01
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 13:21:47
User entered 'USA-US126-2020-mRNA-1273-P301000003'	(b) (4), (b) (6)	06 Nov 2020 13:21:35

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:47

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:59
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:06:01
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 15:09:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 15:09:22
Data point term sent to Coder	System	05 Nov 2020 15:08:39
User entered 'Fatigue'	(b) (4), (b) (6)	05 Nov 2020 15:08:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:47

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:59
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 13:38:12
User closed query 'Per sponsor review, SAE resulted in inpatient hospitalization. Please update field accordingly.' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 05:13:54
Query 'Per sponsor review, SAE resulted in inpatient hospitalization. Please update field accordingly.' answered with 'updated ' (Site from DM).	Krishna Shah (b) (4) (b) (4)	30 Dec 2020 16:56:20
DataPoint Un-verified.	Krishna Shah (b) (4) (b) (4)	30 Dec 2020 16:56:09
User entered 'Yes (Y)' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	30 Dec 2020 16:56:09
User opened query 'Per sponsor review, SAE resulted in inpatient hospitalization. Please update field accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 15:08:25
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:06:01
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 15:08:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:47

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:59
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:06:01
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 15:08:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:47

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:59
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:06:01
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 15:08:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:59
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:06:01
User entered '26 Sep 2020'	(b) (4), (b) (6)	05 Nov 2020 15:08:08



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:47

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:59
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:06:01
User entered '15:00'	(b) (4), (b) (6)	05 Nov 2020 15:08:08

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:56:47**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:59
User entered '26 Sep 2020 15:00'	System	05 Nov 2020 15:08:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:59
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:06:01
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 15:08:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:47

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:59
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:06:01
User entered '28 Sep 2020'	(b) (4), (b) (6)	05 Nov 2020 15:08:08

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:56:47**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:59
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:06:01
User entered '00:00'	(b) (4), (b) (6)	05 Nov 2020 15:08:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:47

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:59
User entered '28 Sep 2020 00:00'	System	05 Nov 2020 15:08:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:47

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:59
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:06:01
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	05 Nov 2020 15:08:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:47

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:59
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:05:37
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	10 Nov 2020 22:11:17
DataPoint Un-verified.	Kelly Woodell (b) (4)	10 Nov 2020 22:11:17
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Kelly Woodell (b) (4)	10 Nov 2020 22:11:17
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).	(b) (4) System	10 Nov 2020 22:11:00
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:06:01
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	05 Nov 2020 15:08:24
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 15:08:24
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	05 Nov 2020 15:08:08
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 15:08:08



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:47

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:59
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:06:01
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 15:08:08

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Folder: Adverse Events

Form: Adverse Events (2)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:59
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:06:01
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 15:08:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:59
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:05:36
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	10 Nov 2020 22:11:00
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	10 Nov 2020 22:11:00
DataPoint Un-verified.	Kelly Woodell (b) (4)	10 Nov 2020 22:11:00
User entered '0' reason for change: Data Entry Error	(b) (4) Kelly Woodell (b) (4)	10 Nov 2020 22:11:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:06:01
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	05 Nov 2020 15:08:08
User entered '1'	(b) (4), (b) (6)	05 Nov 2020 15:08:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:47

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:59
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:06:01
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 15:08:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:47

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:59
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:06:01
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 15:08:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:47

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:59
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:06:01
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 15:08:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:47

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:59
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:06:01
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 15:08:08

US3822278

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:59
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:06:01
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 15:08:08



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:59
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:06:01
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 15:08:08

US3822278

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:47

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:59
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:06:01
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 15:08:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:47

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:59
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 13:38:27
User closed query 'Per CDM: Per page 42 of CCGs version 3.0, "Not Applicable" is to be recorded ONLY "before first dose of IP". Please review and update accordingly. Thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 10:49:23
Query 'Per CDM: Per page 42 of CCGs version 3.0, "Not Applicable" is to be recorded ONLY "before first dose of IP". Please review and update accordingly. Thank you. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 12:28:16
DataPoint Un-verified.	(b) (4), (b) (6)	28 Dec 2020 12:28:11
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Dec 2020 12:28:11
User opened query 'Per CDM: Per page 42 of CCGs version 3.0, "Not Applicable" is to be recorded ONLY "before first dose of IP". Please review and update accordingly. Thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 08:49:19
User closed query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 16:58:23
Query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 12:48:34
User opened query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 08:23:15

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:47

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:06:01
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	05 Nov 2020 15:08:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:47

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:59
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 13:38:32
User closed query 'Per CDM: Per page 42 of CCGs version 3.0, "Not Applicable" is to be recorded ONLY "before first dose of IP". Please review and update accordingly. Thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 10:49:25
Query 'Per CDM: Per page 42 of CCGs version 3.0, "Not Applicable" is to be recorded ONLY "before first dose of IP". Please review and update accordingly. Thank you. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 12:28:20
DataPoint Un-verified.	(b) (4), (b) (6)	28 Dec 2020 12:28:11
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Dec 2020 12:28:11
User opened query 'Per CDM: Per page 42 of CCGs version 3.0, "Not Applicable" is to be recorded ONLY "before first dose of IP". Please review and update accordingly. Thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 08:49:26
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:06:01
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	05 Nov 2020 15:08:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:47

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:59
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
User closed query 'PV Query: As the last dose of mRNA-1273 was given on 25 Sep 2020 (prior to event onset - Fatigue), please update the action taken with mRNA-1273 for the event of Fatigue from none to not applicable. Please leave query open until information is received.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:48:12
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:05:45
Query 'PV Query: As the last dose of mRNA-1273 was given on 25 Sep 2020 (prior to event onset - Fatigue), please update the action taken with mRNA-1273 for the event of Fatigue from none to not applicable. Please leave query open until information is received.' answered with 'UPDATED' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 12:48:56
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 12:48:52
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 12:48:52
User opened query 'PV Query: As the last dose of mRNA-1273 was given on 25 Sep 2020 (prior to event onset - Fatigue), please update the action taken with mRNA-1273 for the event of Fatigue from none to not applicable. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 19:55:29
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:06:01
User entered 'None (NONE)'	(b) (4), (b) (6)	05 Nov 2020 15:08:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:47

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:59
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 13:38:56
DataPoint Un-verified.	Krishna Shah (b) (4)	17 Dec 2020 22:19:36
User entered '1' reason for change: Data Entry Error	(b) (4) Krishna Shah (b) (4)	17 Dec 2020 22:19:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:05:49
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 12:48:52
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 12:48:52
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 19:08:23
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	10 Nov 2020 22:11:00
DataPoint Un-verified.	Kelly Woodell (b) (4)	10 Nov 2020 22:11:00
User entered '1' reason for change: Data Entry Error	(b) (4) Kelly Woodell (b) (4)	10 Nov 2020 22:11:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:06:01
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	05 Nov 2020 15:08:08
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 15:08:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:47

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:59
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 13:38:57
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 08:49:16
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'no conmeds were given for fatigue. ' (Site from DM).	Krishna Shah (b) (4) (b) (4)	17 Dec 2020 22:19:40
DataPoint Un-verified.	Krishna Shah (b) (4) (b) (4)	17 Dec 2020 22:19:36
User entered '0' reason for change: Data Entry Error	Krishna Shah (b) (4) (b) (4)	17 Dec 2020 22:19:36
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 06:08:36
User closed query 'Per CRIO source, conmed of Saline with Magnesium was used to treat AE/SAE. Please reconcile and update if applicable.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 21:05:56
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:05:53
Query 'Per CRIO source, conmed of Saline with Magnesium was used to treat AE/SAE. Please reconcile and update if applicable.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 12:49:07



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:47

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	23 Nov 2020 12:48:52
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 12:48:52
User opened query 'Per CRIO source, conmed of Saline with Magnesium was used to treat AE/SAE. Please reconcile and update if applicable.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 19:19:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 20:06:01
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 15:08:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:47

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:59
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:06:01
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 15:08:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:47

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:59
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:06:01
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	05 Nov 2020 15:08:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:47

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:59
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:06:01
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 15:08:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:47

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:59
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 18:59:33
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	(b) (4)	
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	10 Nov 2020 22:11:17
DataPoint Verified.	System	10 Nov 2020 22:11:17
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 20:06:01
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 15:08:24
		05 Nov 2020 15:08:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:47

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:59
User entered '0'	System	10 Nov 2020 22:11:17
User entered '1'	System	05 Nov 2020 15:08:24
User entered '0'	System	05 Nov 2020 15:08:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:47

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:59
User entered '1'	System	30 Dec 2020 16:56:09
User entered '0'	System	05 Nov 2020 15:08:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:56:47

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 17:11:59



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:56:47

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:13:59
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User closed query 'Per DM CLR: Per Diary Dose 2 Day 3, medication was taken for PAIN AT INJECTION SITE AND HEADACHE on 27SEP2020, however, there is no corresponding Con Med recorded that matches this indication (Pain at Injection Site and Headache) within this timeframe. Please reconcile and update the Con Med eCRF to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 05:55:41
User closed query 'Per DM CLR: Per Diary Dose 1 Day 2 (27AUG2020), Pain at Injection Site = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Con Med recorded that matches this indication (Pain at Injection Site) within this timeframe. Please reconcile and update the Con Med eCRF to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 05:55:29
Query 'Per DM CLR: Per Diary Dose 2 Day 3, medication was taken for PAIN AT INJECTION SITE AND HEADACHE on 27SEP2020, however, there is no corresponding Con Med recorded that matches this indication (Pain at Injection Site and Headache) within this timeframe. Please reconcile and update the Con Med eCRF to record the medication given as appropriate, otherwise clarify. ' answered with 'Per source, medication was not taken for pain at injection site or headache. Medication was taken in relation to medical history.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 15:12:18

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:56:47

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Query 'Per DM CLR: Per Diary Dose 1 Day 2 (27AUG2020), Pain at Injection Site = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Con Med recorded that matches this indication (Pain at Injection Site) within this timeframe. Please reconcile and update the Con Med eCRF to record the medication given as appropriate, otherwise clarify.'	(b) (4), (b) (6)	05 Feb 2021 15:09:38
answered with 'Per source, per day 8 phone call, no medication was reported by the patient. ' (Site from DM).		
User opened query 'Per DM CLR: Per Diary Dose 2 Day 3, medication was taken for PAIN AT INJECTION SITE AND HEADACHE on 27SEP2020, however, there is no corresponding Con Med recorded that matches this indication (Pain at Injection Site and Headache) within this timeframe. Please reconcile and update the Con Med eCRF to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 07:46:03
User opened query 'Per DM CLR: Per Diary Dose 1 Day 2 (27AUG2020), Pain at Injection Site = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Con Med recorded that matches this indication (Pain at Injection Site) within this timeframe. Please reconcile and update the Con Med eCRF to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 07:45:55
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 19:03:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 16:04:51

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:56:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:25:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: COMBINATIONS OF ORAL BLOOD GLUCOSE LOWERING DRUGS, PRODUCT: METFORMIN HYDROCHLORIDE;SITAGLIPTIN, PRODUCTSYNONYM: JANUMET [METFORMIN HYDROCHLORIDE;SITAGLIPTIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 08:00:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 08:00:47
Data point term sent to Coder	System	23 Sep 2020 16:06:16
User entered 'Janument'	(b) (4), (b) (6)	23 Sep 2020 16:05:48

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:56:47**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:25:05
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 16:05:48

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:56:47**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:25:07
User entered 'Diabetes'	(b) (4), (b) (6)	23 Sep 2020 16:05:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:56:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:10:06
Signature has been broken.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:13:47
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User closed query 'Per CRIO Medical History Source, Dose per administration is 50-1000mg. Please reconcile and update if applicable.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:06:24
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:06:22
Query 'Per CRIO Medical History Source, Dose per administration is 50-1000mg. Please reconcile and update if applicable.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 12:44:51
User entered '500-1000' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 12:44:45
User opened query 'Per CRIO Medical History Source, Dose per administration is 50-1000mg. Please reconcile and update if applicable.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 19:26:16
User entered '1000'	(b) (4), (b) (6)	23 Sep 2020 16:05:48

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:56:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:26:19
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Sep 2020 16:05:48

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:56:47**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:26:24
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:05:48



US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:56:47**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:26:25
User entered 'twice daily (BID)'	(b) (4), (b) (6)	23 Sep 2020 16:05:48

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:56:47**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:26:29
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:05:48

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:56:47**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:26:27
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Sep 2020 16:05:48

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:56:47**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:27:09
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:05:48

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:56:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:27:11
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:05:48

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:56:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:27:16
User entered 'I'	(b) (4), (b) (6)	23 Sep 2020 16:05:48

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:56:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:27:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 16:05:48

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:56:47**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:27:19
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:05:48



US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:56:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:27:21
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 16:05:48

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:56:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Sep 2020 16:05:48

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 16:05:48

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 16:05:48

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:47

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: PREGABALIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 15:14:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 15:14:02
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	07 Apr 2021 15:13:13 07 Apr 2021 15:12:37
User signature succeeded.	Christina Kennelly (b) (4) (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	18 Nov 2020 19:30:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: PREGABALIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 07:47:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 07:47:53
Data point term sent to Coder User entered 'Pregabalin'	System (b) (4), (b) (6)	23 Sep 2020 16:07:16 23 Sep 2020 16:06:49

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:30:43
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 16:06:49

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:10:06
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 15:12:37
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 15:12:37
User entered 'Neuropathy' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 15:12:37
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 19:30:45
User entered 'UNK'	(b) (4), (b) (6)	23 Sep 2020 16:06:49

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:56:47**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:30:48
User entered '75'	(b) (4), (b) (6)	23 Sep 2020 16:06:49



US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:30:50
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Sep 2020 16:06:49

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:56:47**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:30:52
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:06:49

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:31:04
User entered 'twice daily (BID)'	(b) (4), (b) (6)	23 Sep 2020 16:06:49

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:56:47**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:31:08
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:06:49

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:56:47**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:31:16
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Sep 2020 16:06:49

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:56:47**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:31:17
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:06:49

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:10:06
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 15:12:37
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 15:12:37
User entered '05 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 15:12:37
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 19:31:19
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:06:49

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:47

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:10:06
	(b) (4)	
User closed query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System).	System	07 Apr 2021 15:12:46
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 15:12:46
	(b) (4), (b) (6)	07 Apr 2021 15:12:46
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 15:12:46
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 15:12:46
User opened query 'Start date is provided, however Start date completely unknown is checked. Please correct.' (Site from System).	System	07 Apr 2021 15:12:37
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 19:31:21
User entered '1'	(b) (4), (b) (6)	23 Sep 2020 16:06:49



US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:56:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:31:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 16:06:49

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:56:47**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:31:25
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:06:49

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:56:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:31:26
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 16:06:49

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:56:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Sep 2020 16:06:49

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 16:06:49

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 16:06:49

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:31:54
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:47:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:47:21
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	05 Nov 2020 16:46:34 05 Nov 2020 16:46:05
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 16:08:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 16:08:38
Data point term sent to Coder User entered 'Fluticasone'	System (b) (4), (b) (6)	23 Sep 2020 16:08:17 23 Sep 2020 16:07:31

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:31:56
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 16:07:31



US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:32:00
User closed query ""Per DM CLR: Please update the indication to reflect the location/type of ALLERGIES. Please reconcile with the AE and Med History eCRFs as appropriate.	(b) (4), (b) (6)	10 Nov 2020 11:09:54
"		
' (Site from DM).		
Query ""Per DM CLR: Please update the indication to reflect the location/type of ALLERGIES. Please reconcile with the AE and Med History eCRFs as appropriate.	(b) (4), (b) (6)	05 Nov 2020 16:46:09
"		
' answered with 'UPDATED' (Site from DM).		
User entered 'SEASONAL ALLERGIES' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 16:46:05
User opened query ""Per DM CLR: Please update the indication to reflect the location/type of ALLERGIES. Please reconcile with the AE and Med History eCRFs as appropriate.	(b) (4), (b) (6)	27 Oct 2020 09:22:20
"		
' (Site from DM).		
User entered 'Allergies'	(b) (4), (b) (6)	23 Sep 2020 16:07:31

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:56:47**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:32:09
User entered '50'	(b) (4), (b) (6)	23 Sep 2020 16:07:31

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:32:11
User entered 'ug (ug)'	(b) (4), (b) (6)	23 Sep 2020 16:07:31

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:56:47**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:32:12
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:07:31

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:32:15
User entered 'as needed (PRN)'	(b) (4), (b) (6)	23 Sep 2020 16:07:31

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:56:47**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:32:17
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:07:31

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:56:47**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:32:18
User entered 'Nasal (NASAL)'	(b) (4), (b) (6)	23 Sep 2020 16:07:31

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:56:47**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:32:21
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:07:31



US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:56:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:32:23
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:07:31

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:56:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:32:25
User entered 'I'	(b) (4), (b) (6)	23 Sep 2020 16:07:31

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:56:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:32:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 16:07:31

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:56:47**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:32:29
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:07:31

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:56:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:32:31
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 16:07:31

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:56:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 16:07:31

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 16:07:31

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 16:07:31



US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:47

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 19:32:56
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE PROPIONATE;SALMETEROL XINAFOATE, PRODUCTSYNONYM: ADVAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 16:48:23
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 16:48:23
	(b) (4)	
Data point term sent to Coder	System	05 Nov 2020 16:47:36
Coding entries removed.	(b) (4), (b) (6)	05 Nov 2020 16:46:57
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE PROPIONATE;SALMETEROL XINAFOATE, PRODUCTSYNONYM: ADVAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 16:08:38
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 16:08:38
	(b) (4)	
Data point term sent to Coder	System	23 Sep 2020 16:08:18
User entered 'Advair'	(b) (4), (b) (6)	23 Sep 2020 16:08:06

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:56:47**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:32:58
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 16:08:06

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:56:47**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:32:59
User entered 'Asthma'	(b) (4), (b) (6)	23 Sep 2020 16:08:06

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:56:47**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:33:01
User entered '100/50'	(b) (4), (b) (6)	23 Sep 2020 16:08:06

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:33:04
User closed query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 10:17:26
Query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 16:46:46
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 16:46:41
User opened query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 09:20:09
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Sep 2020 16:08:06

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:56:47**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:33:06
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:08:06

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:56:47**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:33:08
User entered 'as needed (PRN)'	(b) (4), (b) (6)	23 Sep 2020 16:08:06

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:56:47**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:33:11
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:08:06



US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 19:33:12
User closed query 'Per DM CLR: Please review route, as this is not the expected route for this medication. Please review and correct as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 12:47:59
Query 'Per DM CLR: Please review route, as this is not the expected route for this medication. Please review and correct as appropriate. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 16:47:02
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 16:46:57
User opened query 'Per DM CLR: Please review route, as this is not the expected route for this medication. Please review and correct as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 09:20:11
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Sep 2020 16:08:06

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:56:47**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:33:15
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:08:06

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:56:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:33:17
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:08:06

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:56:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:33:18
User entered 'I'	(b) (4), (b) (6)	23 Sep 2020 16:08:06

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:33:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 16:08:06

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:56:47**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:33:22
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:08:06

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:56:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:33:23
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 16:08:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 16:08:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 16:08:21
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 16:08:06
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:08:06

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:56:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 16:08:06



US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 16:08:06

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 16:08:06

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:56:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:33:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 16:12:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 16:12:40
Data point term sent to Coder	System	23 Sep 2020 16:11:31
User entered 'Omeprazole'	(b) (4), (b) (6)	23 Sep 2020 16:11:18

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:56:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:33:45
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 16:11:18

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:56:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:33:48
User entered 'reflux'	(b) (4), (b) (6)	23 Sep 2020 16:11:18

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:56:47**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:33:50
User entered '20'	(b) (4), (b) (6)	23 Sep 2020 16:11:18

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:56:47**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:33:56
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Sep 2020 16:11:18

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:56:47**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:34:00
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:11:18



US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:56:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:34:02
User entered 'once daily (QD)'	(b) (4), (b) (6)	23 Sep 2020 16:11:18

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:56:47**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:34:04
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:11:18

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:56:47**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:34:05
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Sep 2020 16:11:18

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:56:47**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:34:07
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:11:18

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:56:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:34:09
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:11:18

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:56:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:34:11
User entered 'I'	(b) (4), (b) (6)	23 Sep 2020 16:11:18

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:56:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:34:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 16:11:18

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:56:47**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:34:15
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:11:18



US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:56:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:34:17
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 16:11:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 16:11:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 16:11:26
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 16:11:18
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:11:18

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:56:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 16:11:18

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 16:11:18

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 16:11:18

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: SYNTHROID - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Nov 2020 12:47:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 12:47:52
Data point term sent to Coder	System	23 Nov 2020 12:46:34
Coding entries removed.	(b) (4), (b) (6)	23 Nov 2020 12:46:04
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 19:34:30
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: SYNTHROID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 16:13:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 16:13:37
Data point term sent to Coder	System	23 Sep 2020 16:12:39
User entered 'Synthroid'	(b) (4), (b) (6)	23 Sep 2020 16:12:03

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:56:47**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:34:34
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 16:12:03

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:47

Indication

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM). Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'added to med hx ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 05:54:40
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 15:04:06
User closed query 'Please update if indication is known.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 21:06:47
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:06:45
Query 'Please update if indication is known.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 12:46:11
User entered 'HYPOTHYROIDISM' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 12:46:04
User opened query 'Please update if indication is known.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 19:35:16
User entered 'UNK'	(b) (4), (b) (6)	23 Sep 2020 16:12:03

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:56:47**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:35:20
User entered '50'	(b) (4), (b) (6)	23 Sep 2020 16:12:03



US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:35:22
User entered 'ug (ug)'	(b) (4), (b) (6)	23 Sep 2020 16:12:03

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:56:47**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:35:27
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:12:03

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:35:29
User entered 'once daily (QD)'	(b) (4), (b) (6)	23 Sep 2020 16:12:03

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:56:47**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:35:31
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:12:03

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:56:47**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:35:34
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Sep 2020 16:12:03

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:56:47**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:35:35
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:12:03

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:56:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:35:37
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:12:03

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:35:39
User entered 'I'	(b) (4), (b) (6)	23 Sep 2020 16:12:03



US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:35:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 16:12:03

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:56:47**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:35:44
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:12:03

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:56:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:35:46
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 16:12:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 16:12:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 16:12:10
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 16:12:03
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:12:03

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:56:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 16:12:03

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 16:12:03

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 16:12:03

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:56:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: VENLAFAXINE HYDROCHLORIDE, PRODUCTSYNONYM: EFFEXOR - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Nov 2020 07:13:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 07:13:08
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 19:36:03
Data point term sent to Coder	System	05 Nov 2020 16:49:40
Data point term sent to Coder	System	05 Nov 2020 16:48:39
Coding entries removed.	(b) (4), (b) (6)	05 Nov 2020 16:48:30
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: VENLAFAXINE HYDROCHLORIDE, PRODUCTSYNONYM: EFFEXOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 12:13:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 12:13:41
Data point term sent to Coder	System	23 Sep 2020 16:13:40
User entered 'Effexor'	(b) (4), (b) (6)	23 Sep 2020 16:13:12

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:56:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:36:05
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 16:13:12



US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:56:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
Query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Jan 2021 03:49:59
User opened query 'Per DM CLR: Please update the indication of this medication to include the underlying medical condition/diagnosis that this medication is used for. Update Con Med eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 03:49:55
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 19:36:09
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 11:13:07
User entered 'HORMONE REPLACEMENT THERAPY - POST MENOPAUSAL' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 16:49:00
Query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 16:48:37
User entered 'Hormone Replacement Therapy' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 16:48:30
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the usual use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 09:21:59
User entered 'HRT replacement'	(b) (4), (b) (6)	23 Sep 2020 16:13:12

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:56:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:36:11
User entered '150'	(b) (4), (b) (6)	23 Sep 2020 16:13:12

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:56:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:36:14
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Sep 2020 16:13:12

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:56:47**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:36:18
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:13:12

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:56:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:36:20
User entered 'once daily (QD)'	(b) (4), (b) (6)	23 Sep 2020 16:13:12

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:56:47**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:36:22
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:13:12

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:56:47**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:36:24
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Sep 2020 16:13:12

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:56:47**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:36:26
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:13:12



US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:56:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:36:29
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:13:12

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:56:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:36:32
User entered 'I'	(b) (4), (b) (6)	23 Sep 2020 16:13:12

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:56:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:36:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 16:13:12

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:56:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:36:35
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:13:12

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:56:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:36:37
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 16:13:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Sep 2020 16:13:19
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 16:13:19
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 16:13:12
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:13:12

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:56:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 16:13:12

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 16:13:12

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 16:13:12



US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:56:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 19:36:58
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 16:15:39
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 16:15:39
	(b) (4)	
Data point term sent to Coder	System	23 Sep 2020 16:14:42
User entered 'Clopidogrel'	(b) (4), (b) (6)	23 Sep 2020 16:13:54

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:56:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:37:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 16:13:54

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:56:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:37:02
User entered 'Stroke prevention'	(b) (4), (b) (6)	23 Sep 2020 16:13:54

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:56:47**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:37:05
User entered '75'	(b) (4), (b) (6)	23 Sep 2020 16:13:54

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:56:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:37:07
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Sep 2020 16:13:54

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:56:47**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:37:09
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:13:54

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:56:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:37:11
User entered 'once daily (QD)'	(b) (4), (b) (6)	23 Sep 2020 16:13:54

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:56:47**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:37:14
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:13:54



US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:56:47**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:37:16
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Sep 2020 16:13:54

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:56:47**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:37:17
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:13:54

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:56:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:37:20
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:13:54

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:56:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:37:22
User entered 'I'	(b) (4), (b) (6)	23 Sep 2020 16:13:54

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:56:47**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:37:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 16:13:54

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:56:47**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:37:26
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:13:54

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:56:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:37:28
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 16:13:54

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:56:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 16:13:54



US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 16:13:54

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 16:13:54

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:56:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:37:42
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: OMEGA-3-ACID ETHYL ESTER, PRODUCTSYNONYM: LOVAZA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 11:07:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 11:07:37
Data point term sent to Coder	System	23 Sep 2020 16:15:45
User entered 'Lovaxa'	(b) (4), (b) (6)	23 Sep 2020 16:14:45

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:56:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:37:43
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 16:14:45

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:56:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:37:45
User entered 'UNK'	(b) (4), (b) (6)	23 Sep 2020 16:14:45

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:56:47**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:37:47
User entered 'I'	(b) (4), (b) (6)	23 Sep 2020 16:14:45

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:56:47**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:37:52
User entered 'g (g)'	(b) (4), (b) (6)	23 Sep 2020 16:14:45

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:56:47**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:38:00
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:14:45



US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:56:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:38:03
User entered 'twice daily (BID)'	(b) (4), (b) (6)	23 Sep 2020 16:14:45

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:56:47**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:38:05
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:14:45

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:56:47**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:38:07
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Sep 2020 16:14:45

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:56:47**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:38:09
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:14:45

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:56:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:38:11
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:14:45

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:56:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:38:13
User entered 'I'	(b) (4), (b) (6)	23 Sep 2020 16:14:45

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:56:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:38:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 16:14:45

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:56:47**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:38:17
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:14:45



US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:56:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:38:19
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 16:14:45

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:56:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Sep 2020 16:14:45

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 16:14:45

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 16:14:45

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:56:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 19:38:33
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 16:52:22
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 16:52:22
	(b) (4)	
Data point term sent to Coder Coding entries removed.	System	05 Nov 2020 16:51:45
	(b) (4), (b) (6)	05 Nov 2020 16:50:59
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Sep 2020 10:57:39
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Sep 2020 10:57:39
	(b) (4)	
Data point term sent to Coder User entered 'Rosuvastatin'	System	23 Sep 2020 16:15:45
	(b) (4), (b) (6)	23 Sep 2020 16:15:15

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:56:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:38:35
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 16:15:15

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:56:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:38:42
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 11:13:35
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 16:51:07
User entered 'HIGH TRIGLYCERIDES' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 16:50:59
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than the action of the medication. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 10:23:07
User entered 'Triglycerides'	(b) (4), (b) (6)	23 Sep 2020 16:15:15

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:56:47**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:38:53
User entered '20'	(b) (4), (b) (6)	23 Sep 2020 16:15:15



US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:56:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:38:55
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Sep 2020 16:15:15

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:56:47**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:38:57
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:15:15

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:56:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:38:59
User entered 'once daily (QD)'	(b) (4), (b) (6)	23 Sep 2020 16:15:15

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:56:47**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:39:02
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:15:15

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:56:47**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:39:12
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Sep 2020 16:15:15

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:56:47**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:39:15
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:15:15

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:56:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:39:17
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:15:15

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:56:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:39:21
User entered 'I'	(b) (4), (b) (6)	23 Sep 2020 16:15:15



US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:56:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:39:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 16:15:15

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:56:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:39:30
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:15:15

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:56:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:39:32
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 16:15:15

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:56:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 16:15:15

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 16:15:15

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 16:15:15

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:56:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:39:47
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) (b) (4)	23 Sep 2020 16:16:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 16:16:35
Data point term sent to Coder User entered 'Losartan'	System (b) (4), (b) (6)	23 Sep 2020 16:15:45 23 Sep 2020 16:15:42

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:56:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:39:49
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 16:15:42



US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:56:47**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:39:51
User entered 'HBP'	(b) (4), (b) (6)	23 Sep 2020 16:15:42

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:56:47**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:39:57
User entered '50'	(b) (4), (b) (6)	23 Sep 2020 16:15:42

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:56:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:40:08
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Sep 2020 16:15:42

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:56:47**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:40:10
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:15:42

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:56:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:40:12
User entered 'once daily (QD)'	(b) (4), (b) (6)	23 Sep 2020 16:15:42

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:56:47**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:40:14
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:15:42

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:56:47**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:40:16
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Sep 2020 16:15:42

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:56:47**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:40:18
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:15:42



US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:56:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:40:20
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:15:42

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:56:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:40:22
User entered 'I'	(b) (4), (b) (6)	23 Sep 2020 16:15:42

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:56:47**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:40:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 16:15:42

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:56:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:40:27
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:15:42

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:56:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:40:31
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 16:15:42

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:56:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 16:15:42

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 16:15:42

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 16:15:42



US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:56:47

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 19:40:50
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: CHONDROITIN;GLUCOSAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 16:53:38
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	05 Nov 2020 16:53:38
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	05 Nov 2020 16:52:46
Coding entries removed.	(b) (4), (b) (6)	05 Nov 2020 16:52:09
	(b) (4), (b) (6)	
User entered 'GLUCOSAMINE/CHONDROITIN'	(b) (4), (b) (6)	05 Nov 2020 16:52:09
reason for change: Data Entry Error		
User coded data point as ATC:	Coder Import (b) (4)	23 Sep 2020 17:28:15
MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: GLUCOSAMINE - version WHODrug-Global-B3\\202003.	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	23 Sep 2020 17:28:15
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	23 Sep 2020 17:26:37
User entered 'Glucosamine'	(b) (4), (b) (6)	23 Sep 2020 17:26:21
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Sep 2020 17:25:37
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	23 Sep 2020 16:16:11

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2032 of 2548

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:56:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:40:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 17:26:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Sep 2020 17:25:37
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	23 Sep 2020 16:16:11

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:56:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:40:56
User entered 'Supplement'	(b) (4), (b) (6)	23 Sep 2020 17:26:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Sep 2020 17:25:37
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	23 Sep 2020 16:16:11

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:56:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:41:00
User closed query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or update the name of medication. Please update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 09:25:46
Query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or update the name of medication. Please update eCRF as appropriate. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 16:52:14
User opened query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or update the name of medication. Please update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 09:23:15
User entered '500/400'	(b) (4), (b) (6)	23 Sep 2020 17:26:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Sep 2020 17:25:37
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	23 Sep 2020 16:16:11

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:56:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:41:06
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Sep 2020 17:26:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Sep 2020 17:25:37
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	23 Sep 2020 16:16:11

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:56:47

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:41:07
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:26:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Sep 2020 17:25:37
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	23 Sep 2020 16:16:11

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:56:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:41:14
User entered 'twice daily (BID)'	(b) (4), (b) (6)	23 Sep 2020 17:26:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Sep 2020 17:25:37
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	23 Sep 2020 16:16:11

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:56:47

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:41:15
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:26:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Sep 2020 17:25:37
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	23 Sep 2020 16:16:11



US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:56:47

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:41:17
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Sep 2020 17:26:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Sep 2020 17:25:37
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	23 Sep 2020 16:16:11

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:56:47

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:41:19
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:26:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Sep 2020 17:25:37
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	23 Sep 2020 16:16:11

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:56:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:41:21
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:26:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Sep 2020 17:25:37
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	23 Sep 2020 16:16:11

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:56:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:41:22
User entered 'I'	(b) (4), (b) (6)	23 Sep 2020 17:26:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Sep 2020 17:25:37
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	23 Sep 2020 16:16:11

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:56:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:41:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 17:26:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Sep 2020 17:25:37
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	23 Sep 2020 16:16:11

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:56:47

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:41:27
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:26:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Sep 2020 17:25:37
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	23 Sep 2020 16:16:11

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:56:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:41:29
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 17:26:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Sep 2020 17:25:37
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	23 Sep 2020 16:16:11

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:56:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Sep 2020 17:26:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Sep 2020 17:25:37
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	23 Sep 2020 16:16:11



US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 17:26:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Sep 2020 17:25:37
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	23 Sep 2020 16:16:11

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 17:26:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	23 Sep 2020 17:25:37
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	23 Sep 2020 16:16:11

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:56:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 19:41:55
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 17:28:47
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 17:28:47
	(b) (4)	
Data point term sent to Coder	System	23 Sep 2020 17:27:39
User entered 'Fish Oil'	(b) (4), (b) (6)	23 Sep 2020 17:27:35

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:56:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:41:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 17:27:35

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:56:47**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:41:58
User entered 'Supplement'	(b) (4), (b) (6)	23 Sep 2020 17:27:35

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:56:47**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:42:00
User entered 'I'	(b) (4), (b) (6)	23 Sep 2020 17:27:35

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:56:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:42:02
User entered 'g (g)'	(b) (4), (b) (6)	23 Sep 2020 17:27:35

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:56:47**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:42:06
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:27:35



US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:56:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:42:08
User entered 'twice daily (BID)'	(b) (4), (b) (6)	23 Sep 2020 17:27:35

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:56:47**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:42:10
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:27:35

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:56:47**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:42:12
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Sep 2020 17:27:35

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:56:47**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:42:14
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:27:35

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:56:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:42:16
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:27:35

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:56:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:42:19
User entered 'I'	(b) (4), (b) (6)	23 Sep 2020 17:27:35

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:56:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:42:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 17:27:35

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:56:47**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:42:22
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:27:35



US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:56:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:42:24
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 17:27:35

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:56:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Sep 2020 17:27:35

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 17:27:35

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 17:27:35

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:56:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 19:43:10
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: BULK-FORMING LAXATIVES, PRODUCT: METHYLCELLULOSE, PRODUCTSYNONYM: CITRUCEL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 17:29:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 17:29:34
Data point term sent to Coder	System	23 Sep 2020 17:28:40
User entered 'Citrucel'	(b) (4), (b) (6)	23 Sep 2020 17:28:12

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:56:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:43:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 17:28:12

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:56:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:43:17
User entered 'Supplement'	(b) (4), (b) (6)	23 Sep 2020 17:28:12

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:56:47**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:43:19
User entered '500'	(b) (4), (b) (6)	23 Sep 2020 17:28:12



US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:56:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:43:21
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Sep 2020 17:28:12

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:56:47**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:43:24
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:28:12

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:56:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:43:26
User entered 'twice daily (BID)'	(b) (4), (b) (6)	23 Sep 2020 17:28:12

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:56:47**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:43:30
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:28:12

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:56:47**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:43:32
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Sep 2020 17:28:12

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:56:47**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:43:34
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:28:12

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:56:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:43:36
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:28:12

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:56:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:43:38
User entered 'I'	(b) (4), (b) (6)	23 Sep 2020 17:28:12



US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:56:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:43:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 17:28:12

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:56:47**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:43:42
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:28:12

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:56:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:43:44
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 17:28:12

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:56:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Sep 2020 17:28:12

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 17:28:12

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 17:28:12

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:56:47

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:43:59
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: HERBAL ANTIBACTERIALS AND ANTIINFECTIVES FOR SYSTEMIC USE, ATC: HERBAL URINARY ANTISEPTICS AND ANTIINFECTIVES, PRODUCT: VACCINIUM MACROCARPON, PRODUCTSYNONYM: ELLURA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 07:18:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 07:18:47
Data point term sent to Coder	System	23 Sep 2020 17:28:41
User entered 'Ellura'	(b) (4), (b) (6)	23 Sep 2020 17:28:37

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:56:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 17:28:37



US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:56:47**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:05
User entered 'Supplement'	(b) (4), (b) (6)	23 Sep 2020 17:28:37

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:56:47**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:09
User entered '36'	(b) (4), (b) (6)	23 Sep 2020 17:28:37

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:56:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:11
User entered 'mg (mg)'	(b) (4), (b) (6)	23 Sep 2020 17:28:37

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:56:47**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:16
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:28:37

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:56:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:17
User entered 'once daily (QD)'	(b) (4), (b) (6)	23 Sep 2020 17:28:37

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:56:47**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:22
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:28:37

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:56:47**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:23
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Sep 2020 17:28:37

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:56:47**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:25
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:28:37



US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:56:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:26
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:28:37

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:56:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:29
User entered 'I'	(b) (4), (b) (6)	23 Sep 2020 17:28:37

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:56:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 17:28:37

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:56:47**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:33
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:28:37

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:56:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:35
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 17:28:37

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:56:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 17:28:37

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 17:28:37

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 17:28:37



US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:56:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 19:44:52
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 17:30:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 17:30:39
Data point term sent to Coder	System	23 Sep 2020 17:29:42
User entered 'Calcium'	(b) (4), (b) (6)	23 Sep 2020 17:29:12

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:56:47**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 17:29:12

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:56:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:45:02
User entered 'Supplement'	(b) (4), (b) (6)	23 Sep 2020 17:29:12

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:56:47**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:45:13
User entered '1200'	(b) (4), (b) (6)	23 Sep 2020 17:29:12

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:56:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User closed query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:56:40
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 19:45:15
Query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate. ' answered with 'Per medical record subject takes 1200 mcg daily' (Site from DM).	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 22:15:36
User opened query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 09:21:35
User entered 'ug (ug)'	(b) (4), (b) (6)	23 Sep 2020 17:29:12

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:56:47**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:45:17
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:29:12

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:56:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:45:19
User entered 'once daily (QD)'	(b) (4), (b) (6)	23 Sep 2020 17:29:12

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:56:47**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:45:22
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:29:12



US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:56:47**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:45:24
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Sep 2020 17:29:12

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:56:47**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:45:26
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:29:12

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:56:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:45:28
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:29:12

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:56:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:45:30
User entered 'I'	(b) (4), (b) (6)	23 Sep 2020 17:29:12

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:56:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:45:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 17:29:12

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:56:47**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:45:34
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:29:12

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:56:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:45:35
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 17:29:12

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:56:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 17:29:12



US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 17:29:12

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 17:29:12

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:56:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:54:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B COMPLEX, PRODUCTSYNONYM: B-COMPLEX [VITAMIN B COMPLEX] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 12:08:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 12:08:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B COMPLEX, PRODUCTSYNONYM: VITAMIN B-COMPLEX [VITAMIN B COMPLEX] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 17:31:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 17:31:41
Data point term sent to Coder User entered 'vitamin B complex'	System (b) (4), (b) (6)	23 Sep 2020 17:30:43 23 Sep 2020 17:29:53

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:56:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:54:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 17:29:53

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:56:47**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:05
User entered 'Supplement'	(b) (4), (b) (6)	23 Sep 2020 17:29:53

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:56:47**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:07
User entered 'I'	(b) (4), (b) (6)	23 Sep 2020 17:29:53

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:56:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:08
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	23 Sep 2020 17:29:53

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:56:47**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:29:53



US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:56:47**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:12
User entered 'once daily (QD)'	(b) (4), (b) (6)	23 Sep 2020 17:29:53

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:56:47

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:13
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:29:53

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:56:47**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:15
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Sep 2020 17:29:53

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:56:47**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:17
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:29:53

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:56:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:19
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:29:53

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:56:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:20
User entered 'I'	(b) (4), (b) (6)	23 Sep 2020 17:29:53

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:56:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 17:29:53

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:56:47**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:24
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:29:53



US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:56:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:26
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 17:29:53

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:56:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 17:29:53

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 17:29:53

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 17:29:53

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:56:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:01:32
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 16:55:26
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 16:55:26
	(b) (4)	
Data point term sent to Coder	System	05 Nov 2020 16:54:52
Coding entries removed.	(b) (4), (b) (6)	05 Nov 2020 16:54:16
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 17:32:39
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 17:32:39
	(b) (4)	
Data point term sent to Coder	System	23 Sep 2020 17:31:45
User entered 'Zyrtec'	(b) (4), (b) (6)	23 Sep 2020 17:31:23

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:56:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:01:34
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 17:31:23

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:56:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User closed query ""Per DM CLR: Please update the indication to reflect the location/type of ALLERGIES. Please reconcile with the AE and Med History eCRFs as appropriate.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:56:53
"		
' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:01:37
Query ""Per DM CLR: Please update the indication to reflect the location/type of ALLERGIES. Please reconcile with the AE and Med History eCRFs as appropriate.	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 22:19:22
"		
' answered with 'Location is unknown' (Site from DM).		
User entered 'SEASONAL ALLERGIES' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 16:54:16
User opened query ""Per DM CLR: Please update the indication to reflect the location/type of ALLERGIES. Please reconcile with the AE and Med History eCRFs as appropriate.	(b) (4), (b) (6)	27 Oct 2020 10:23:29
"		
' (Site from DM). User entered 'Allergies'	(b) (4), (b) (6)	23 Sep 2020 17:31:23

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:56:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 05:54:52
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 15:04:37
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:04:32
User entered '10' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:04:32
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 03:55:02
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:01:39
User entered '1'	(b) (4), (b) (6)	23 Sep 2020 17:31:23



US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:56:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:04:32
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:04:32
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:01:42
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	23 Sep 2020 17:31:23

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:56:47**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:01:44
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:31:23

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:56:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:01:46
User entered 'once daily (QD)'	(b) (4), (b) (6)	23 Sep 2020 17:31:23

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:56:47**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:01:48
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:31:23

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:56:47**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:01:50
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Sep 2020 17:31:23

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:56:47**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:01:53
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:31:23

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:56:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:01:54
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:31:23

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:56:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:02:01
User entered 'I'	(b) (4), (b) (6)	23 Sep 2020 17:31:23



US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:56:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:02:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 17:31:23

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:56:47**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:02:04
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:31:23

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:56:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:02:06
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 17:31:23

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:56:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 17:31:23

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 17:31:23

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 17:31:23

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:56:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:02:23
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: LEVOCETIRIZINE DIHYDROCHLORIDE, PRODUCTSYNONYM: XYZAL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 22:20:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 22:20:42
Data point term sent to Coder	System	10 Nov 2020 22:20:22
Coding entries removed.	Kelly Woodell (b) (4)	10 Nov 2020 22:19:37
	(b) (4)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: LEVOCETIRIZINE DIHYDROCHLORIDE, PRODUCTSYNONYM: XYZAL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 17:33:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 17:33:42
Data point term sent to Coder	System	23 Sep 2020 17:32:47
User entered 'Xyzal'	(b) (4), (b) (6)	23 Sep 2020 17:31:50

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:56:47**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:02:25
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 17:31:50



US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:56:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:02:27
User closed query ""Per DM CLR: Please update the indication to reflect the location/type of ALLERGIES. Please reconcile with the AE and Med History eCRFs as appropriate.	(b) (4), (b) (6)	13 Nov 2020 09:20:33
"		
' (Site from DM).		
Query ""Per DM CLR: Please update the indication to reflect the location/type of ALLERGIES. Please reconcile with the AE and Med History eCRFs as appropriate.	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 22:19:41
"		
' answered with 'added' (Site from DM).		
User entered 'Seasonal ALLERGIES' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	10 Nov 2020 22:19:37
User opened query ""Per DM CLR: Please update the indication to reflect the location/type of ALLERGIES. Please reconcile with the AE and Med History eCRFs as appropriate.	(b) (4), (b) (6)	27 Oct 2020 10:23:40
"		
' (Site from DM).		
User entered 'Allergies'	(b) (4), (b) (6)	23 Sep 2020 17:31:50

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:56:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 05:54:59
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 15:04:54
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:04:49
User entered '5' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:04:49
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 03:54:43
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:02:30
User entered '1'	(b) (4), (b) (6)	23 Sep 2020 17:31:50

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:56:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Feb 2021 15:04:49
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:04:49
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 20:02:31
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	23 Sep 2020 17:31:50

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:56:47**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:02:34
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:31:50

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:56:47**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:02:36
User entered 'once daily (QD)'	(b) (4), (b) (6)	23 Sep 2020 17:31:50

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:56:47**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:02:37
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:31:50

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:56:47**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:04:19
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Sep 2020 17:31:50

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:56:47**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:04:21
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:31:50



US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:56:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:04:23
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:31:50

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:56:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:04:24
User entered 'I'	(b) (4), (b) (6)	23 Sep 2020 17:31:50

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:56:47**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:04:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 17:31:50

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:56:47**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:04:28
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:31:50

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:56:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:04:30
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 17:31:50

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:56:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 17:31:50

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 17:31:50

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 17:31:50



US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:56:47

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 20:04:45
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)	05 Nov 2020 21:14:28
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 21:14:28
	(b) (4)	
Data point term sent to Coder	System	05 Nov 2020 16:55:55
Coding entries removed.	(b) (4), (b) (6)	05 Nov 2020 16:55:35
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)	23 Sep 2020 17:34:46
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 17:34:46
	(b) (4)	
Data point term sent to Coder	System	23 Sep 2020 17:33:48
User entered 'Aspirin'	(b) (4), (b) (6)	23 Sep 2020 17:33:05

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:56:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:04:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 16:55:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 17:33:05

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:56:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:05:01
User closed query ' Per DM CLR: Please review if this medication is given as a prophylaxis or a supplement. If given as a prophylaxis, please update ConMed reason to include the Medical Condition to support the prophylactic indication or if supplement, update Reason for Medication to reflect this information. Update ConMed eCRF as appropriate." ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 11:13:50
Query ' Per DM CLR: Please review if this medication is given as a prophylaxis or a supplement. If given as a prophylaxis, please update ConMed reason to include the Medical Condition to support the prophylactic indication or if supplement, update Reason for Medication to reflect this information. Update ConMed eCRF as appropriate." ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 16:55:40
User entered 'Atherosclerosis of aorta' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 16:55:35
User opened query ' Per DM CLR: Please review if this medication is given as a prophylaxis or a supplement. If given as a prophylaxis, please update ConMed reason to include the Medical Condition to support the prophylactic indication or if supplement, update Reason for Medication to reflect this information. Update ConMed eCRF as appropriate." ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 09:21:06
User entered 'Supplement'	(b) (4), (b) (6)	23 Sep 2020 17:33:05

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:56:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:05:05
User closed query ""Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate.	(b) (4), (b) (6)	09 Nov 2020 10:01:23
' (Site from DM). Query ""Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate.	(b) (4), (b) (6)	05 Nov 2020 16:56:15
' answered with 'updated' (Site from DM). User entered '81' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 16:55:56
User opened query ""Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are various dosage options for this drug. Update Con Med eCRF as appropriate.	(b) (4), (b) (6)	27 Oct 2020 09:21:13
' (Site from DM). User entered '1'	(b) (4), (b) (6)	23 Sep 2020 17:33:05

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:56:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:05:08
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 16:55:56
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	23 Sep 2020 17:33:05

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:56:47**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:05:11
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:33:05

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:56:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:05:13
User entered 'once daily (QD)'	(b) (4), (b) (6)	23 Sep 2020 17:33:05

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:56:47

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:05:20
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:33:05



US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:56:47**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:05:22
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Sep 2020 17:33:05

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:56:47**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:05:23
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:33:05

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:56:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:05:26
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:33:05

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:56:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:05:28
User entered 'I'	(b) (4), (b) (6)	23 Sep 2020 17:33:05

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:56:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:05:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 17:33:05

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:56:47**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:05:32
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:33:05

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:56:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:05:34
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 17:33:05

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:56:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 17:33:05



US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 17:33:05

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 17:33:05

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:56:47

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:29:35
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE, PRODUCTSYNONYM: INFLUENZA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 06:02:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 06:02:25
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:25
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) (b) (4)	01 Nov 2020 21:22:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 21:22:56
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE, PRODUCTSYNONYM: INFLUENZA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 17:45:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 17:45:39
Data point term sent to Coder User entered 'Influenza'	System (b) (4), (b) (6)	23 Sep 2020 17:44:13 23 Sep 2020 17:43:32

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:56:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:29:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Sep 2020 17:43:32

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:56:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:29:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:06:58
User entered 'Vaccine'	(b) (4), (b) (6)	23 Sep 2020 17:43:32

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:56:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:29:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:07:00
User entered 'UNK'	(b) (4), (b) (6)	23 Sep 2020 17:43:32

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:56:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:29:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:07:02
User entered 'mL (mL)'	(b) (4), (b) (6)	23 Sep 2020 17:43:32

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:56:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:29:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:07:05
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:43:32



US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:56:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:29:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:07:06
User entered 'once (ONCE)'	(b) (4), (b) (6)	23 Sep 2020 17:43:32

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:56:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:29:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:07:08
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:43:32

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:56:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:29:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:07:10
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	23 Sep 2020 17:43:32

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:56:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:29:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:07:13
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 17:43:32

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:56:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:29:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:07:14
User entered '1 Sep 2019'	(b) (4), (b) (6)	23 Sep 2020 17:43:32

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:56:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:29:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:07:16
User entered '0'	(b) (4), (b) (6)	23 Sep 2020 17:43:32

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:56:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:29:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:07:19
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 17:43:32

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:56:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:29:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:07:21
User entered '1 Sep 2019'	(b) (4), (b) (6)	23 Sep 2020 17:43:32



US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:56:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:29:35
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 20:07:23
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 17:43:32

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:56:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:29:35
User entered empty.	System	23 Sep 2020 17:43:32

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:29:35
User entered empty.	System	23 Sep 2020 17:43:32

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:29:35
User entered empty.	System	23 Sep 2020 17:43:32

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:56:47

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Nov 2020 19:14:51
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: NITROFURAN DERIVATIVES, PRODUCT: NITROFURANTOIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Nov 2020 16:59:20
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	05 Nov 2020 16:59:20
	(b) (4)	
Data point term sent to Coder	System	05 Nov 2020 16:58:58
User entered 'Nitrofurantoin'	(b) (4), (b) (6)	05 Nov 2020 16:58:09

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:56:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:14:53
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:58:09

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:56:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 05:55:22
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'AE added' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 15:06:50
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 03:53:22
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 19:14:54
User entered 'UTI'	(b) (4), (b) (6)	05 Nov 2020 16:58:09

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:56:47

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:14:56
User entered '100'	(b) (4), (b) (6)	05 Nov 2020 16:58:09



US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:56:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:14:58
User entered 'mg (mg)'	(b) (4), (b) (6)	05 Nov 2020 16:58:09

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:56:47**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:15:00
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 16:58:09

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:56:47

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:15:02
User entered 'twice daily (BID)'	(b) (4), (b) (6)	05 Nov 2020 16:58:09

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:56:47

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:15:04
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 16:58:09

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:56:47**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:15:06
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Nov 2020 16:58:09

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:56:47**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:15:09
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 16:58:09

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:56:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:15:11
User entered '09 Sep 2020'	(b) (4), (b) (6)	05 Nov 2020 16:58:09

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:56:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:15:12
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 16:58:09



US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:56:47

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:15:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 16:58:09

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:56:47**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:15:17
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 16:58:09

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:56:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:15:19
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:58:09

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:56:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Nov 2020 16:58:09

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 16:58:09

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Nov 2020 16:58:09

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:56:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:29:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, PRODUCT: MAGNESIUM;SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Nov 2020 12:50:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 12:50:53
Data point term sent to Coder	System	23 Nov 2020 12:47:34
Coding entries removed.	(b) (4), (b) (6)	23 Nov 2020 12:46:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, PRODUCT: MAGNESIUM;SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 09:35:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 09:35:12
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 19:15:38
Data point term sent to Coder	System	05 Nov 2020 17:00:01
User entered 'Saline with Magnesium'	(b) (4), (b) (6)	05 Nov 2020 16:59:04

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:56:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:29:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:15:41
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:59:04



US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:56:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:29:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:07:18
User closed query 'Please reconcile with CRIO source. SAE is noted in CRIO and EDC as Dehydration. Please update both CRIO and EDC if applicable.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 21:07:16
Query 'Please reconcile with CRIO source. SAE is noted in CRIO and EDC as Dehydration. Please update both CRIO and EDC if applicable.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 12:46:51
User entered 'DEHYDRATION - SAE' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 12:46:47
User opened query 'Please reconcile with CRIO source. SAE is noted in CRIO and EDC as Dehydration. Please update both CRIO and EDC if applicable.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 19:16:43
User entered 'SAE - FALL'	(b) (4), (b) (6)	05 Nov 2020 16:59:04

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:56:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:29:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:16:46
User entered 'unk'	(b) (4), (b) (6)	05 Nov 2020 16:59:04

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:56:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:29:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:16:50
User entered 'mL (mL)'	(b) (4), (b) (6)	05 Nov 2020 16:59:04

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:56:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:29:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:16:52
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 16:59:04

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:56:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:29:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:16:54
User entered 'twice daily (BID)'	(b) (4), (b) (6)	05 Nov 2020 16:59:04

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:56:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:29:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:17:02
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 16:59:04

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:56:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:29:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:17:04
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	05 Nov 2020 16:59:04

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:56:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:29:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:17:07
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 16:59:04



US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:56:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:29:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:17:08
User entered '27 Sep 2020'	(b) (4), (b) (6)	05 Nov 2020 16:59:04

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:56:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:29:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:17:10
User entered '0'	(b) (4), (b) (6)	05 Nov 2020 16:59:04

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:56:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:29:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:17:12
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:59:04

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:56:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:29:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:17:14
User entered '29 Sep 2020'	(b) (4), (b) (6)	05 Nov 2020 16:59:04

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:56:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:29:40
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:17:19
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 16:59:04

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:56:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:29:40
User entered '2'	System	05 Nov 2020 16:59:04

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:29:40
User entered '1'	System	05 Nov 2020 16:59:04

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:29:40
User entered '804 (804)'	System	05 Nov 2020 16:59:04



US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:56:47

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC ACETATE;ZINC GLUCONATE, PRODUCTSYNONYM: ZICAM COLD REMEDY [ZINC ACETATE;ZINC GLUCONATE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	16 Mar 2021 11:51:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 11:51:49
Data point term sent to Coder	System	03 Mar 2021 13:24:07
User closed query '	System	03 Mar 2021 13:23:12
DM-Coding: please update the eCRF to include the active ingredient name(s) in brackets next to the drug. ' (Site from System).		
Query '	(b) (4), (b) (6)	03 Mar 2021 13:23:12
DM-Coding: please update the eCRF to include the active ingredient name(s) in brackets next to the drug. ' answered with 'updated' (Site from System).		
Data point term sent to Coder	System	03 Mar 2021 13:23:06
User entered 'ZICAM (zinc acetate and zinc gluconate)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Mar 2021 13:22:19
User opened query '	Coder Import (b) (4) (b) (4)	03 Mar 2021 13:07:58
DM-Coding: please update the eCRF to include the active ingredient name(s) in brackets next to the drug. ' (Site from System).		
Data point term sent to Coder	System	23 Feb 2021 15:33:43
User entered 'Zicam'	(b) (4), (b) (6)	23 Feb 2021 15:33:16

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:56:47

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 15:33:16

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:56:47**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered 'Common Cold'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 15:33:16

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:56:47**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered 'unk'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 15:33:16

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:56:47

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 15:33:16

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:56:47**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 15:33:16

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:56:47**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 15:33:16

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:56:47**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 15:33:16



US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:56:47**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 15:33:16

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:56:47**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 15:33:16

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:56:47**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 15:33:16

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:56:47**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 15:33:16

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:56:47**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 15:33:16

US3822278

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:56:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 15:33:16

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:56:47**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 15:33:16

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:56:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Feb 2021 15:33:16



US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Feb 2021 15:33:16

US3822278

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:56:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Feb 2021 15:33:16

US3822278

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:56:47

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:13:59
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Un-verified.	Krishna Shah (b) (4)	17 Dec 2020 22:12:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Krishna Shah (b) (4)	17 Dec 2020 22:12:08
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 13:30:01
User entered 'No (N)'	Kelly Woodell (b) (4)	23 Nov 2020 23:34:39

US3822278

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:56:47**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
User entered '27 Sep 2020'	Krishna Shah (b) (4)	17 Dec 2020 22:12:38
	(b) (4)	

US3822278

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:56:47

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
User entered 'Lumbar Puncture'	Krishna Shah (b) (4)	17 Dec 2020 22:12:38
	(b) (4)	

US3822278

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:56:47

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Krishna Shah (b) (4) (b) (4)	17 Dec 2020 22:12:38

US3822278

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:56:47**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
User entered empty.	Krishna Shah (b) (4)	17 Dec 2020 22:12:38
	(b) (4)	

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered	System	29 Sep 2020 13:36:15
'USA-US126-2020-MRNA-1273-P301000003'		



US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Yes (Y)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Death

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Yes (Y)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Christina'	System	29 Sep 2020 13:36:15



US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Kennelly'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 18:19:16
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:09
	(b) (4)	
Query 'Please complete all address fields.' answered with 'Completed' (Site from CRA).	Kelly Woodell (b) (4)	19 Feb 2021 16:33:08
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 15:26:57
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:43:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:46
	(b) (4)	
Query 'Please complete all address fields.' answered with 'complete' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 15:12:56
	(b) (4)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4)	
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 15:07:22
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:04
	(b) (4)	

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Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: [Street](#)

Audit	User	Time (GMT)
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 21:08:02
Query 'Please complete all address fields.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 12:47:56
User entered '6060 PIEDMONT ROW DRIVE SOUTH'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 19:03:52

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:10
	(b) (4)	
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:47
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
User entered 'CHARLOTTE' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:07
	(b) (4), (b) (6)	
User entered 'CHARLOTTE'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
	(b) (4), (b) (6)	

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Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:12
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:50
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:48
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:10
	(b) (4), (b) (6)	
User entered 'NORTH CAROLINA'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
	(b) (4), (b) (6)	

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:14
	(b) (4)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:52
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:50
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:12
	(b) (4), (b) (6)	
User entered '28210'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
	(b) (4), (b) (6)	

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Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 12:05:23
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:29:11
User entered 'US'	System	29 Sep 2020 13:37:30

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	08 Feb 2021 19:49:29
User entered '11'	System	08 Feb 2021 12:14:21
User entered '10'	System	04 Jan 2021 19:48:52
User entered '9'	System	24 Nov 2020 19:08:51
User entered '8'	System	24 Nov 2020 14:48:37
User entered '7'	System	12 Nov 2020 00:56:56
User entered '6'	System	06 Nov 2020 13:22:22
User entered '5'	System	06 Nov 2020 13:13:06
User entered '4'	System	05 Nov 2020 13:36:20
User entered '3'	System	16 Oct 2020 12:51:46
User entered '2'	System	15 Oct 2020 12:05:31
User entered '1'	System	29 Sep 2020 13:37:30



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Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'USA-US126-2020-MRNA-1273-P301000003'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Yes (Y)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Death

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Yes (Y)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15



US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Christina'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Kennelly'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 18:19:16
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:09
	(b) (4)	
Query 'Please complete all address fields.' answered with 'Completed' (Site from CRA).	Kelly Woodell (b) (4)	19 Feb 2021 16:33:08
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 15:26:57
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:43:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:46
	(b) (4)	
Query 'Please complete all address fields.' answered with 'complete' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 15:12:56
	(b) (4)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4)	
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 15:07:22
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:04
	(b) (4)	

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: [Street](#)

Audit	User	Time (GMT)
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 21:08:02
Query 'Please complete all address fields.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 12:47:56
User entered '6060 PIEDMONT ROW DRIVE SOUTH'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 19:03:52

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:10
	(b) (4)	
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:47
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
User entered 'CHARLOTTE' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:07
	(b) (4), (b) (6)	
User entered 'CHARLOTTE'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
	(b) (4), (b) (6)	

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Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:12
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:50
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:48
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:10
	(b) (4), (b) (6)	
User entered 'NORTH CAROLINA'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
	(b) (4), (b) (6)	

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Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:14
	(b) (4)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:52
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:50
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:12
	(b) (4), (b) (6)	
User entered '28210'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
	(b) (4), (b) (6)	

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Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 12:05:23
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:29:11
User entered 'US'	System	29 Sep 2020 13:37:30



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Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	08 Feb 2021 19:49:29
User entered '11'	System	08 Feb 2021 12:14:21
User entered '10'	System	04 Jan 2021 19:48:52
User entered '9'	System	24 Nov 2020 19:08:51
User entered '8'	System	24 Nov 2020 14:48:37
User entered '7'	System	12 Nov 2020 00:56:56
User entered '6'	System	06 Nov 2020 13:22:22
User entered '5'	System	06 Nov 2020 13:13:06
User entered '4'	System	05 Nov 2020 13:36:20
User entered '3'	System	16 Oct 2020 12:51:46
User entered '2'	System	15 Oct 2020 12:05:31
User entered '1'	System	29 Sep 2020 13:37:30

**US3822278**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:56:47**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
User entered '29/Sep/2020 09:37'	System	29 Sep 2020 13:37:30

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:56:47

**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.**

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 12:05:23
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:29:11
User entered 'I'	(b) (4), (b) (6)	29 Sep 2020 13:37:30

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'USA-US126-2020-MRNA-1273-P301000003'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Yes (Y)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Death

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Yes (Y)'	System	29 Sep 2020 13:36:15



US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Christina'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Kennelly'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 18:19:16
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:09
	(b) (4)	
Query 'Please complete all address fields.' answered with 'Completed' (Site from CRA).	Kelly Woodell (b) (4)	19 Feb 2021 16:33:08
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 15:26:57
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:43:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:46
	(b) (4)	
Query 'Please complete all address fields.' answered with 'complete' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 15:12:56
	(b) (4)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4)	
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 15:07:22
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:04
	(b) (4)	

**US3822278**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:47**

[Site Address: Street](#)

Audit	User	Time (GMT)
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 21:08:02
Query 'Please complete all address fields.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 12:47:56
User entered '6060 PIEDMONT ROW DRIVE SOUTH'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 19:03:52

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:10
	(b) (4)	
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:47
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
User entered 'CHARLOTTE' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:07
	(b) (4), (b) (6)	
User entered 'CHARLOTTE'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
	(b) (4), (b) (6)	



US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:12
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:50
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:48
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:10
	(b) (4), (b) (6)	
User entered 'NORTH CAROLINA'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
	(b) (4), (b) (6)	

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Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:14
	(b) (4)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:52
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:50
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:12
	(b) (4), (b) (6)	
User entered '28210'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
	(b) (4), (b) (6)	

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 12:05:23
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:29:11
User entered 'US'	System	29 Sep 2020 13:37:30

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	08 Feb 2021 19:49:29
User entered '11'	System	08 Feb 2021 12:14:21
User entered '10'	System	04 Jan 2021 19:48:52
User entered '9'	System	24 Nov 2020 19:08:51
User entered '8'	System	24 Nov 2020 14:48:37
User entered '7'	System	12 Nov 2020 00:56:56
User entered '6'	System	06 Nov 2020 13:22:22
User entered '5'	System	06 Nov 2020 13:13:06
User entered '4'	System	05 Nov 2020 13:36:20
User entered '3'	System	16 Oct 2020 12:51:46
User entered '2'	System	15 Oct 2020 12:05:31
User entered '1'	System	29 Sep 2020 13:37:30

**US3822278**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:56:47**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:51:58
User entered '15/Oct/2020 08:05'	System	15 Oct 2020 12:05:31

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:56:47

**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.**

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 20:52:00
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:51:37
User entered 'I'	(b) (4), (b) (6)	15 Oct 2020 12:05:31

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered	System	29 Sep 2020 13:36:15
'USA-US126-2020-MRNA-1273-P301000003'		

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Yes (Y)'	System	29 Sep 2020 13:36:15



US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Death

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Yes (Y)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Christina'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Kennelly'	System	29 Sep 2020 13:36:15



US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 18:19:16
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:09
	(b) (4)	
Query 'Please complete all address fields.' answered with 'Completed' (Site from CRA).	Kelly Woodell (b) (4)	19 Feb 2021 16:33:08
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 15:26:57
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:43:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:46
	(b) (4)	
Query 'Please complete all address fields.' answered with 'complete' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 15:12:56
	(b) (4)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4)	
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 15:07:22
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:04
	(b) (4)	

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: [Street](#)

Audit	User	Time (GMT)
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 21:08:02
Query 'Please complete all address fields.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 12:47:56
User entered '6060 PIEDMONT ROW DRIVE SOUTH'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 19:03:52

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:10
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:47
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
User entered 'CHARLOTTE' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:07
User entered 'CHARLOTTE'	(b) (4), (b) (6)	23 Nov 2020 12:47:51

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:12
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:50
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:48
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:10
	(b) (4), (b) (6)	
User entered 'NORTH CAROLINA'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
	(b) (4), (b) (6)	

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:14
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:52
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:50
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:12
User entered '28210'	(b) (4), (b) (6)	23 Nov 2020 12:47:51

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 12:05:23
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:29:11
User entered 'US'	System	29 Sep 2020 13:37:30

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	08 Feb 2021 19:49:29
User entered '11'	System	08 Feb 2021 12:14:21
User entered '10'	System	04 Jan 2021 19:48:52
User entered '9'	System	24 Nov 2020 19:08:51
User entered '8'	System	24 Nov 2020 14:48:37
User entered '7'	System	12 Nov 2020 00:56:56
User entered '6'	System	06 Nov 2020 13:22:22
User entered '5'	System	06 Nov 2020 13:13:06
User entered '4'	System	05 Nov 2020 13:36:20
User entered '3'	System	16 Oct 2020 12:51:46
User entered '2'	System	15 Oct 2020 12:05:31
User entered '1'	System	29 Sep 2020 13:37:30

**US3822278**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 09:56:47**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 20:52:08
User entered '16/Oct/2020 12:51'	System	16 Oct 2020 12:51:46



US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:56:47

**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.**

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 13:36:08
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 20:52:10
User entered 'I'	(b) (4), (b) (6)	16 Oct 2020 12:51:46

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered	System	29 Sep 2020 13:36:15
'USA-US126-2020-MRNA-1273-P301000003'		

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Yes (Y)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Death

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Yes (Y)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15



US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Christina'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Kennelly'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 18:19:16
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:09
	(b) (4)	
Query 'Please complete all address fields.' answered with 'Completed' (Site from CRA).	Kelly Woodell (b) (4)	19 Feb 2021 16:33:08
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 15:26:57
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:43:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:46
	(b) (4)	
Query 'Please complete all address fields.' answered with 'complete' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 15:12:56
	(b) (4)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4)	
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 15:07:22
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:04
	(b) (4)	

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Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: [Street](#)

Audit	User	Time (GMT)
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 21:08:02
Query 'Please complete all address fields.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 12:47:56
User entered '6060 PIEDMONT ROW DRIVE SOUTH'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 19:03:52

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:10
	(b) (4)	
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:47
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
User entered 'CHARLOTTE' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:07
	(b) (4), (b) (6)	
User entered 'CHARLOTTE'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
	(b) (4), (b) (6)	

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Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:12
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:50
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:48
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:10
	(b) (4), (b) (6)	
User entered 'NORTH CAROLINA'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
	(b) (4), (b) (6)	

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:14
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:52
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:50
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:12
User entered '28210'	(b) (4), (b) (6)	23 Nov 2020 12:47:51



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Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 12:05:23
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:29:11
User entered 'US'	System	29 Sep 2020 13:37:30

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	08 Feb 2021 19:49:29
User entered '11'	System	08 Feb 2021 12:14:21
User entered '10'	System	04 Jan 2021 19:48:52
User entered '9'	System	24 Nov 2020 19:08:51
User entered '8'	System	24 Nov 2020 14:48:37
User entered '7'	System	12 Nov 2020 00:56:56
User entered '6'	System	06 Nov 2020 13:22:22
User entered '5'	System	06 Nov 2020 13:13:06
User entered '4'	System	05 Nov 2020 13:36:20
User entered '3'	System	16 Oct 2020 12:51:46
User entered '2'	System	15 Oct 2020 12:05:31
User entered '1'	System	29 Sep 2020 13:37:30

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:56:47

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:08:27
User entered '05/Nov/2020 13:36'	System	05 Nov 2020 13:36:20

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:56:47

**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.**

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 21:08:27
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 13:12:54
User entered 'I'	(b) (4), (b) (6)	05 Nov 2020 13:36:20

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered	System	29 Sep 2020 13:36:15
'USA-US126-2020-MRNA-1273-P301000003'		

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Yes (Y)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Death

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15



US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Yes (Y)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Christina'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Kennelly'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 18:19:16
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:09
	(b) (4)	
Query 'Please complete all address fields.' answered with 'Completed' (Site from CRA).	Kelly Woodell (b) (4)	19 Feb 2021 16:33:08
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 15:26:57
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:43:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:46
	(b) (4)	
Query 'Please complete all address fields.' answered with 'complete' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 15:12:56
	(b) (4)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4)	
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 15:07:22
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:04
	(b) (4)	

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: [Street](#)

Audit	User	Time (GMT)
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 21:08:02
Query 'Please complete all address fields.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 12:47:56
User entered '6060 PIEDMONT ROW DRIVE SOUTH'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 19:03:52



US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:10
	(b) (4)	
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:47
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
User entered 'CHARLOTTE' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:07
	(b) (4), (b) (6)	
User entered 'CHARLOTTE'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
	(b) (4), (b) (6)	

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Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:12
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:50
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:48
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:10
	(b) (4), (b) (6)	
User entered 'NORTH CAROLINA'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
	(b) (4), (b) (6)	

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Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:14
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:52
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:50
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:12
User entered '28210'	(b) (4), (b) (6)	23 Nov 2020 12:47:51

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Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 12:05:23
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:29:11
User entered 'US'	System	29 Sep 2020 13:37:30

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	08 Feb 2021 19:49:29
User entered '11'	System	08 Feb 2021 12:14:21
User entered '10'	System	04 Jan 2021 19:48:52
User entered '9'	System	24 Nov 2020 19:08:51
User entered '8'	System	24 Nov 2020 14:48:37
User entered '7'	System	12 Nov 2020 00:56:56
User entered '6'	System	06 Nov 2020 13:22:22
User entered '5'	System	06 Nov 2020 13:13:06
User entered '4'	System	05 Nov 2020 13:36:20
User entered '3'	System	16 Oct 2020 12:51:46
User entered '2'	System	15 Oct 2020 12:05:31
User entered '1'	System	29 Sep 2020 13:37:30

**US3822278**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (5)**

**Generated On: 10 Jun 2021 09:56:47**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:08:27
User entered '06/Nov/2020 13:13'	System	06 Nov 2020 13:13:06

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:56:47

**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.**

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 21:08:27
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 13:22:11
User entered 'I'	(b) (4), (b) (6)	06 Nov 2020 13:13:06

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

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[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered	System	29 Sep 2020 13:36:15
'USA-US126-2020-MRNA-1273-P301000003'		



US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Yes (Y)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Death

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Yes (Y)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Christina'	System	29 Sep 2020 13:36:15



US3822278

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Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Kennelly'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 18:19:16
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:09
	(b) (4)	
Query 'Please complete all address fields.' answered with 'Completed' (Site from CRA).	Kelly Woodell (b) (4)	19 Feb 2021 16:33:08
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 15:26:57
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:43:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:46
	(b) (4)	
Query 'Please complete all address fields.' answered with 'complete' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 15:12:56
	(b) (4)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4)	
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 15:07:22
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:04
	(b) (4)	

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: [Street](#)

Audit	User	Time (GMT)
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 21:08:02
Query 'Please complete all address fields.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 12:47:56
User entered '6060 PIEDMONT ROW DRIVE SOUTH'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 19:03:52

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:10
	(b) (4)	
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:47
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
User entered 'CHARLOTTE' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:07
	(b) (4), (b) (6)	
User entered 'CHARLOTTE'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
	(b) (4), (b) (6)	

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:12
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:50
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:48
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:10
	(b) (4), (b) (6)	
User entered 'NORTH CAROLINA'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
	(b) (4), (b) (6)	

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:14
	(b) (4)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:52
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:50
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:12
	(b) (4), (b) (6)	
User entered '28210'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
	(b) (4), (b) (6)	

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 12:05:23
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:29:11
User entered 'US'	System	29 Sep 2020 13:37:30

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	08 Feb 2021 19:49:29
User entered '11'	System	08 Feb 2021 12:14:21
User entered '10'	System	04 Jan 2021 19:48:52
User entered '9'	System	24 Nov 2020 19:08:51
User entered '8'	System	24 Nov 2020 14:48:37
User entered '7'	System	12 Nov 2020 00:56:56
User entered '6'	System	06 Nov 2020 13:22:22
User entered '5'	System	06 Nov 2020 13:13:06
User entered '4'	System	05 Nov 2020 13:36:20
User entered '3'	System	16 Oct 2020 12:51:46
User entered '2'	System	15 Oct 2020 12:05:31
User entered '1'	System	29 Sep 2020 13:37:30



**US3822278**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (6)**

**Generated On: 10 Jun 2021 09:56:47**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:08:27
User entered '06/Nov/2020 13:22'	System	06 Nov 2020 13:22:22

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:56:47

**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.**

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:08:27
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 00:56:40
User entered 'I'	(b) (4), (b) (6)	06 Nov 2020 13:22:22

**US3822278**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:47**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered	System	29 Sep 2020 13:36:15
'USA-US126-2020-MRNA-1273-P301000003'		

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Yes (Y)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Death

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Yes (Y)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15



US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Christina'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Kennelly'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 18:19:16
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:09
	(b) (4)	
Query 'Please complete all address fields.' answered with 'Completed' (Site from CRA).	Kelly Woodell (b) (4)	19 Feb 2021 16:33:08
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 15:26:57
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:43:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:46
	(b) (4)	
Query 'Please complete all address fields.' answered with 'complete' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 15:12:56
	(b) (4)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4)	
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 15:07:22
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:04
	(b) (4)	

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Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: [Street](#)

Audit	User	Time (GMT)
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 21:08:02
Query 'Please complete all address fields.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 12:47:56
User entered '6060 PIEDMONT ROW DRIVE SOUTH'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 19:03:52

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Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:10
	(b) (4)	
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:47
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
User entered 'CHARLOTTE' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:07
	(b) (4), (b) (6)	
User entered 'CHARLOTTE'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
	(b) (4), (b) (6)	

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:12
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:50
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:48
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:10
	(b) (4), (b) (6)	
User entered 'NORTH CAROLINA'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
	(b) (4), (b) (6)	



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Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:14
	(b) (4)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:52
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:50
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:12
	(b) (4), (b) (6)	
User entered '28210'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
	(b) (4), (b) (6)	

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 12:05:23
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:29:11
User entered 'US'	System	29 Sep 2020 13:37:30

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	08 Feb 2021 19:49:29
User entered '11'	System	08 Feb 2021 12:14:21
User entered '10'	System	04 Jan 2021 19:48:52
User entered '9'	System	24 Nov 2020 19:08:51
User entered '8'	System	24 Nov 2020 14:48:37
User entered '7'	System	12 Nov 2020 00:56:56
User entered '6'	System	06 Nov 2020 13:22:22
User entered '5'	System	06 Nov 2020 13:13:06
User entered '4'	System	05 Nov 2020 13:36:20
User entered '3'	System	16 Oct 2020 12:51:46
User entered '2'	System	15 Oct 2020 12:05:31
User entered '1'	System	29 Sep 2020 13:37:30

**US3822278**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (7)**

**Generated On: 10 Jun 2021 09:56:47**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:08:27
User entered '12/Nov/2020 00:56'	System	12 Nov 2020 00:56:56

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:56:47

**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.**

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:27
User entered 'I'	(b) (4), (b) (6)	12 Nov 2020 00:56:56

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'USA-US126-2020-MRNA-1273-P301000003'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Yes (Y)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Death

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15



US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Yes (Y)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Christina'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Kennelly'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 18:19:16
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:09
	(b) (4)	
Query 'Please complete all address fields.' answered with 'Completed' (Site from CRA).	Kelly Woodell (b) (4)	19 Feb 2021 16:33:08
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 15:26:57
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:43:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:46
	(b) (4)	
Query 'Please complete all address fields.' answered with 'complete' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 15:12:56
	(b) (4)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4)	
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 15:07:22
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:04
	(b) (4)	



US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: [Street](#)

Audit	User	Time (GMT)
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 21:08:02
Query 'Please complete all address fields.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 12:47:56
User entered '6060 PIEDMONT ROW DRIVE SOUTH'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 19:03:52

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Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:10
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:47
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
User entered 'CHARLOTTE' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:07
User entered 'CHARLOTTE'	(b) (4), (b) (6)	23 Nov 2020 12:47:51

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Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:12
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:50
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:48
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:10
	(b) (4), (b) (6)	
User entered 'NORTH CAROLINA'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
	(b) (4), (b) (6)	

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Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:14
	(b) (4)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:52
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:50
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:12
	(b) (4), (b) (6)	
User entered '28210'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
	(b) (4), (b) (6)	

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Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 12:05:23
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:29:11
User entered 'US'	System	29 Sep 2020 13:37:30

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	08 Feb 2021 19:49:29
User entered '11'	System	08 Feb 2021 12:14:21
User entered '10'	System	04 Jan 2021 19:48:52
User entered '9'	System	24 Nov 2020 19:08:51
User entered '8'	System	24 Nov 2020 14:48:37
User entered '7'	System	12 Nov 2020 00:56:56
User entered '6'	System	06 Nov 2020 13:22:22
User entered '5'	System	06 Nov 2020 13:13:06
User entered '4'	System	05 Nov 2020 13:36:20
User entered '3'	System	16 Oct 2020 12:51:46
User entered '2'	System	15 Oct 2020 12:05:31
User entered '1'	System	29 Sep 2020 13:37:30

**US3822278**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (8)**

**Generated On: 10 Jun 2021 09:56:47**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:58:39
User entered '24/Nov/2020 14:48'	System	24 Nov 2020 14:48:37

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:56:47

**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.**

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:58:39
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
User entered 'I'	(b) (4), (b) (6)	24 Nov 2020 14:48:37



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Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered	System	29 Sep 2020 13:36:15
'USA-US126-2020-MRNA-1273-P301000003'		

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Yes (Y)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Death

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Yes (Y)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15



US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Christina'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Kennelly'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 18:19:16
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:09
	(b) (4)	
Query 'Please complete all address fields.' answered with 'Completed' (Site from CRA).	Kelly Woodell (b) (4)	19 Feb 2021 16:33:08
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 15:26:57
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:43:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:46
	(b) (4)	
Query 'Please complete all address fields.' answered with 'complete' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 15:12:56
	(b) (4)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4)	
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 15:07:22
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:04
	(b) (4)	

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Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: [Street](#)

Audit	User	Time (GMT)
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 21:08:02
Query 'Please complete all address fields.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 12:47:56
User entered '6060 PIEDMONT ROW DRIVE SOUTH'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 19:03:52

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:10
	(b) (4)	
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:47
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
User entered 'CHARLOTTE' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:07
	(b) (4), (b) (6)	
User entered 'CHARLOTTE'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
	(b) (4), (b) (6)	

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Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:12
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:50
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:48
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:10
	(b) (4), (b) (6)	
User entered 'NORTH CAROLINA'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
	(b) (4), (b) (6)	

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Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:14
	(b) (4)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:52
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:50
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:12
	(b) (4), (b) (6)	
User entered '28210'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
	(b) (4), (b) (6)	

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Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 12:05:23
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:29:11
User entered 'US'	System	29 Sep 2020 13:37:30



US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	08 Feb 2021 19:49:29
User entered '11'	System	08 Feb 2021 12:14:21
User entered '10'	System	04 Jan 2021 19:48:52
User entered '9'	System	24 Nov 2020 19:08:51
User entered '8'	System	24 Nov 2020 14:48:37
User entered '7'	System	12 Nov 2020 00:56:56
User entered '6'	System	06 Nov 2020 13:22:22
User entered '5'	System	06 Nov 2020 13:13:06
User entered '4'	System	05 Nov 2020 13:36:20
User entered '3'	System	16 Oct 2020 12:51:46
User entered '2'	System	15 Oct 2020 12:05:31
User entered '1'	System	29 Sep 2020 13:37:30

**US3822278**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (9)**

**Generated On: 10 Jun 2021 09:56:47**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:58:39
User entered '24/Nov/2020 19:08'	System	24 Nov 2020 19:08:51

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 09:56:47

**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.**

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:49:02
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
User entered 'I'	(b) (4), (b) (6)	24 Nov 2020 19:08:51

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered	System	29 Sep 2020 13:36:15
'USA-US126-2020-MRNA-1273-P301000003'		

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Yes (Y)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Death

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Yes (Y)'	System	29 Sep 2020 13:36:15



US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Christina'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Kennelly'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 18:19:16
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:09
	(b) (4)	
Query 'Please complete all address fields.' answered with 'Completed' (Site from CRA).	Kelly Woodell (b) (4)	19 Feb 2021 16:33:08
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 15:26:57
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:43:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:46
	(b) (4)	
Query 'Please complete all address fields.' answered with 'complete' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 15:12:56
	(b) (4)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4)	
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 15:07:22
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:04
	(b) (4)	

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: [Street](#)

Audit	User	Time (GMT)
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 21:08:02
Query 'Please complete all address fields.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 12:47:56
User entered '6060 PIEDMONT ROW DRIVE SOUTH'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 19:03:52

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:10
	(b) (4)	
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:47
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
User entered 'CHARLOTTE' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:07
	(b) (4), (b) (6)	
User entered 'CHARLOTTE'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
	(b) (4), (b) (6)	



US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:12
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:50
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:48
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:10
	(b) (4), (b) (6)	
User entered 'NORTH CAROLINA'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
	(b) (4), (b) (6)	

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Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:14
	(b) (4)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:52
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:50
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:12
	(b) (4), (b) (6)	
User entered '28210'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
	(b) (4), (b) (6)	

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Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 12:05:23
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:29:11
User entered 'US'	System	29 Sep 2020 13:37:30

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	08 Feb 2021 19:49:29
User entered '11'	System	08 Feb 2021 12:14:21
User entered '10'	System	04 Jan 2021 19:48:52
User entered '9'	System	24 Nov 2020 19:08:51
User entered '8'	System	24 Nov 2020 14:48:37
User entered '7'	System	12 Nov 2020 00:56:56
User entered '6'	System	06 Nov 2020 13:22:22
User entered '5'	System	06 Nov 2020 13:13:06
User entered '4'	System	05 Nov 2020 13:36:20
User entered '3'	System	16 Oct 2020 12:51:46
User entered '2'	System	15 Oct 2020 12:05:31
User entered '1'	System	29 Sep 2020 13:37:30

**US3822278**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (10)**

**Generated On: 10 Jun 2021 09:56:47**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 13:37:05
User entered '04/Jan/2021 14:48'	System	04 Jan 2021 19:48:52

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form (10)

Generated On: 10 Jun 2021 09:56:47

**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.**

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 13:37:05
Reviewed for Safety.	(b) (4), (b) (6)	04 Jan 2021 19:49:02
User entered 'I'	(b) (4), (b) (6)	04 Jan 2021 19:48:52

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered	System	29 Sep 2020 13:36:15
'USA-US126-2020-MRNA-1273-P301000003'		

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Yes (Y)'	System	29 Sep 2020 13:36:15



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Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Death

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Yes (Y)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Christina'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Kennelly'	System	29 Sep 2020 13:36:15



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Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 18:19:16
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:09
	(b) (4)	
Query 'Please complete all address fields.' answered with 'Completed' (Site from CRA).	Kelly Woodell (b) (4)	19 Feb 2021 16:33:08
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 15:26:57
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:43:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:46
	(b) (4)	
Query 'Please complete all address fields.' answered with 'complete' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 15:12:56
	(b) (4)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4)	
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 15:07:22
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:04
	(b) (4)	

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Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: [Street](#)

Audit	User	Time (GMT)
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 21:08:02
Query 'Please complete all address fields.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 12:47:56
User entered '6060 PIEDMONT ROW DRIVE SOUTH'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 19:03:52

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Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:10
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:47
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
User entered 'CHARLOTTE' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:07
User entered 'CHARLOTTE'	(b) (4), (b) (6)	23 Nov 2020 12:47:51

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Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:12
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:50
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:48
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:10
	(b) (4), (b) (6)	
User entered 'NORTH CAROLINA'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
	(b) (4), (b) (6)	

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Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:14
	(b) (4)	
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:52
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:50
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:12
	(b) (4), (b) (6)	
User entered '28210'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
	(b) (4), (b) (6)	

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 12:05:23
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:29:11
User entered 'US'	System	29 Sep 2020 13:37:30

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	08 Feb 2021 19:49:29
User entered '11'	System	08 Feb 2021 12:14:21
User entered '10'	System	04 Jan 2021 19:48:52
User entered '9'	System	24 Nov 2020 19:08:51
User entered '8'	System	24 Nov 2020 14:48:37
User entered '7'	System	12 Nov 2020 00:56:56
User entered '6'	System	06 Nov 2020 13:22:22
User entered '5'	System	06 Nov 2020 13:13:06
User entered '4'	System	05 Nov 2020 13:36:20
User entered '3'	System	16 Oct 2020 12:51:46
User entered '2'	System	15 Oct 2020 12:05:31
User entered '1'	System	29 Sep 2020 13:37:30

**US3822278**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (11)**

**Generated On: 10 Jun 2021 09:56:47**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:19:26
User entered '08/Feb/2021 12:14'	System	08 Feb 2021 12:14:21



US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form (11)

Generated On: 10 Jun 2021 09:56:47

**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.**

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 18:19:26
User entered 'I'	(b) (4), (b) (6)	08 Feb 2021 12:14:21

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered	System	29 Sep 2020 13:36:15
'USA-US126-2020-MRNA-1273-P301000003'		

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Yes (Y)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Death

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Yes (Y)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15



US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'No (N)'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Christina'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:29:11
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:36:33
User entered 'Kennelly'	System	29 Sep 2020 13:36:15

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 18:19:16
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:09
	(b) (4)	
Query 'Please complete all address fields.' answered with 'Completed' (Site from CRA).	Kelly Woodell (b) (4)	19 Feb 2021 16:33:08
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	19 Feb 2021 15:26:57
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 17:43:49
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:46
	(b) (4)	
Query 'Please complete all address fields.' answered with 'complete' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 15:12:56
	(b) (4)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4)	
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4)	
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 15:07:22
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:04
	(b) (4)	

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Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: [Street](#)

Audit	User	Time (GMT)
User closed query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 21:08:02
Query 'Please complete all address fields.' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 12:47:56
User entered '6060 PIEDMONT ROW DRIVE SOUTH'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
User opened query 'Please complete all address fields.' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 19:03:52

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Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:10
	(b) (4)	
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:47
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
User entered 'CHARLOTTE' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:46
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:07
	(b) (4), (b) (6)	
User entered 'CHARLOTTE'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
	(b) (4), (b) (6)	

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Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:12
	(b) (4)	
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:50
	(b) (4), (b) (6)	
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
User entered 'NORTH CAROLINA' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:48
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
	(b) (4), (b) (6)	
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:10
	(b) (4), (b) (6)	
User entered 'NORTH CAROLINA'	(b) (4), (b) (6)	23 Nov 2020 12:47:51
	(b) (4), (b) (6)	

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Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:19:14
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:01
	(b) (4)	
Un-reviewed for Safety.	System	08 Feb 2021 12:14:21
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 12:14:08
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:43:52
Un-reviewed for Safety.	(b) (4), (b) (6)	05 Feb 2021 15:12:51
User entered '28210' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Feb 2021 15:12:51
DataPoint Un-verified.	(b) (4), (b) (6)	05 Feb 2021 15:06:50
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:58:39
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 19:08:36
Un-reviewed for Safety.	System	24 Nov 2020 14:48:37
DataPoint Un-verified.	System	24 Nov 2020 14:48:37
User entered empty.	System	24 Nov 2020 14:48:37
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 14:48:22
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 21:08:12
User entered '28210'	(b) (4), (b) (6)	23 Nov 2020 12:47:51



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Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 12:05:23
DataPoint Verified.	(b) (4), (b) (6)	08 Oct 2020 19:29:11
User entered 'US'	System	29 Sep 2020 13:37:30

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	08 Feb 2021 19:49:29
User entered '11'	System	08 Feb 2021 12:14:21
User entered '10'	System	04 Jan 2021 19:48:52
User entered '9'	System	24 Nov 2020 19:08:51
User entered '8'	System	24 Nov 2020 14:48:37
User entered '7'	System	12 Nov 2020 00:56:56
User entered '6'	System	06 Nov 2020 13:22:22
User entered '5'	System	06 Nov 2020 13:13:06
User entered '4'	System	05 Nov 2020 13:36:20
User entered '3'	System	16 Oct 2020 12:51:46
User entered '2'	System	15 Oct 2020 12:05:31
User entered '1'	System	29 Sep 2020 13:37:30

**US3822278**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (12)**

**Generated On: 10 Jun 2021 09:56:47**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:19:26
User entered '08/Feb/2021 14:49'	System	08 Feb 2021 19:49:29

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000003

Form: Safety Report Form (12)

Generated On: 10 Jun 2021 09:56:47

**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.**

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 18:19:26
User entered 'I'	(b) (4), (b) (6)	08 Feb 2021 19:49:29

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:58:55
User entered 'USA-US126-2020-MRNA-1273-P301000009'	System	24 Nov 2020 19:08:16

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:58:55
User entered 'No (N)'	System	24 Nov 2020 19:08:16

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Death

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:58:55
User entered 'No (N)'	System	24 Nov 2020 19:08:16

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:58:55
User entered 'No (N)'	System	24 Nov 2020 19:08:16



**US3822278**

**Folder: SAE USA-US126-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:56:47**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:58:55
User entered 'No (N)'	System	24 Nov 2020 19:08:16

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:58:55
User entered 'No (N)'	System	24 Nov 2020 19:08:16

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:58:55
User entered 'No (N)'	System	24 Nov 2020 19:08:16

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:58:55
User entered 'No (N)'	System	24 Nov 2020 19:08:16

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:58:55
User entered 'Christina'	System	24 Nov 2020 19:08:16

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:58:55
User entered 'Kennelly'	System	24 Nov 2020 19:08:16

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:16:44
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:38
	(b) (4)	
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 15:07:41
User closed query 'Please complete each address field.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 20:53:28
Query 'Please complete each address field.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 14:39:08
User entered '6060 PIEDMONT ROW DRIVE SOUTH'	(b) (4), (b) (6)	26 Jan 2021 14:39:02
User opened query 'Please complete each address field.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 16:21:02

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:16:46
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	19 Feb 2021 16:33:38
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 15:07:43
User entered 'CHARLOTTE'	(b) (4), (b) (6)	26 Jan 2021 14:39:02



US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:16:47
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:38
	(b) (4)	
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 15:07:45
User entered 'NORTH CAROLINA'	(b) (4), (b) (6)	26 Jan 2021 14:39:02

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:16:49
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:38
	(b) (4)	
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 15:07:47
User entered '28210'	(b) (4), (b) (6)	26 Jan 2021 14:39:02

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:58:55
User entered 'US'	System	24 Nov 2020 19:08:51

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 14:39:02

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:58:55
User entered 'USA-US126-2020-MRNA-1273-P301000009'	System	24 Nov 2020 19:08:16

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Serious

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:58:55
User entered 'No (N)'	System	24 Nov 2020 19:08:16

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Death

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:58:55
User entered 'No (N)'	System	24 Nov 2020 19:08:16

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:58:55
User entered 'No (N)'	System	24 Nov 2020 19:08:16



US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:58:55
User entered 'No (N)'	System	24 Nov 2020 19:08:16

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:58:55
User entered 'No (N)'	System	24 Nov 2020 19:08:16

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:58:55
User entered 'No (N)'	System	24 Nov 2020 19:08:16

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:58:55
User entered 'No (N)'	System	24 Nov 2020 19:08:16

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:58:55
User entered 'Christina'	System	24 Nov 2020 19:08:16

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:58:55
User entered 'Kennelly'	System	24 Nov 2020 19:08:16

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:16:44
User entered '6060 Piedmont Row Drive South' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:38
	(b) (4)	
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 15:07:41
User closed query 'Please complete each address field.' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 20:53:28
Query 'Please complete each address field.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 14:39:08
User entered '6060 PIEDMONT ROW DRIVE SOUTH'	(b) (4), (b) (6)	26 Jan 2021 14:39:02
User opened query 'Please complete each address field.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 16:21:02

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 18:16:46
User entered 'Charlotte' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:38
DataPoint Un-verified.	(b) (4)	
User entered empty.	System	08 Feb 2021 12:14:21
DataPoint Verified.	System	08 Feb 2021 12:14:21
	(b) (4), (b) (6)	05 Feb 2021 15:07:43
User entered 'CHARLOTTE'	(b) (4), (b) (6)	26 Jan 2021 14:39:02



US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:16:47
User entered 'NC' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:38
	(b) (4)	
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 15:07:45
User entered 'NORTH CAROLINA'	(b) (4), (b) (6)	26 Jan 2021 14:39:02

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:16:49
User entered '28210' reason for change: Data Entry Error	Kelly Woodell (b) (4)	19 Feb 2021 16:33:38
	(b) (4)	
DataPoint Un-verified.	System	08 Feb 2021 12:14:21
User entered empty.	System	08 Feb 2021 12:14:21
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 15:07:47
User entered '28210'	(b) (4), (b) (6)	26 Jan 2021 14:39:02

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:58:55
User entered 'US'	System	24 Nov 2020 19:08:51

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:56:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 14:39:02

US3822278

Folder: SAE USA-US126-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:56:47

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 21:58:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 18:17:00
DataPoint Un-verified.	Kelly Woodell (b) (4)	19 Feb 2021 16:34:08
	(b) (4)	
User entered '02/Oct/2020 00:00' reason for change:	Kelly Woodell (b) (4)	19 Feb 2021 16:34:08
Data Entry Error	(b) (4)	
User closed query 'Please confirm if this was submitted.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 19:44:40
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 19:44:28
Query 'Please confirm if this was submitted.'	Kelly Woodell (b) (4)	05 Feb 2021 18:11:55
answered with 'added' (Site from CRA).	(b) (4)	
DataPoint Un-verified.	Kelly Woodell (b) (4)	05 Feb 2021 18:11:48
	(b) (4)	
User entered '02/Oct/2020 :' (non-conformant).	Kelly Woodell (b) (4)	05 Feb 2021 18:11:48
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Feb 2021 17:45:39
User opened query 'Please confirm if this was submitted.' (Site from CRA).	(b) (4), (b) (6)	05 Feb 2021 15:10:16
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 14:39:02