

US3832055 (Prod: Keystone VitaLink Research - Anderson - PPDS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:01:20

All time stamps listed in this document are displayed in GMT

US3832055

Form: Participant Creation

Data signed: (b) (4) 21 Feb 2021 16:59:41

Generated On: 10 Jun 2021 10:01:20

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[Participant ID](#)

US3832055

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

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US3832055

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 14:02:10

Generated On: 10 Jun 2021 10:01:20

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

Visit date (dd MMM yyyy)	03 AUG 2020
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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	SCRN
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US3832055

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 14:02:09

Generated On: 10 Jun 2021 10:01:20

Date of Birth (MMM yyyy)	(b) (6) 1949
Age	71
Age Units	YEARS
Age (Derived)	71
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 14:02:09

Generated On: 10 Jun 2021 10:01:20

Date of Informed Consent ( <i>dd MMM yyyy</i> )	03 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 14:02:09

Generated On: 10 Jun 2021 10:01:20

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 14:02:10

Generated On: 10 Jun 2021 10:01:20

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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) 12 Apr 2021 23:02:12

Generated On: 10 Jun 2021 10:01:20

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Apr 2021 23:02:12

Generated On: 10 Jun 2021 10:01:20

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 12 Apr 2021 23:02:12

Generated On: 10 Jun 2021 10:01:20

Condition	DEGENERATIVE DISC DISEASE
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Start Year (derived)	1999
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3832055

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 12 Apr 2021 23:02:12

Generated On: 10 Jun 2021 10:01:20

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 12 Apr 2021 23:02:12

Generated On: 10 Jun 2021 10:01:20

Condition	ALLERGIC RHINITIS
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 12 Apr 2021 23:02:12

Generated On: 10 Jun 2021 10:01:20

Condition	INTERMITTENT HEADACHES
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 12 Apr 2021 23:02:12

Generated On: 10 Jun 2021 10:01:20

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 12 Apr 2021 23:02:12

Generated On: 10 Jun 2021 10:01:20

Condition	DEVIATED SEPTUM
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN DEC 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	DEC 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 14:02:10

Generated On: 10 Jun 2021 10:01:20

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	03 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	10:41 (24 HR)
Vital Signs Date and Time (derived)	03 AUG 2020 10:41
Height ( <i>xxx.x</i> )	67 in
Weight ( <i>xxx.x</i> )	190 lb
BMI ( <i>xxx.x</i> )	29.82043 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) 15 Feb 2021 14:02:10

Generated On: 10 Jun 2021 10:01:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 14:02:10

Generated On: 10 Jun 2021 10:01:20

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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) 15 Feb 2021 14:02:10

Generated On: 10 Jun 2021 10:01:20

<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) 15 Feb 2021 14:02:10

Generated On: 10 Jun 2021 10:01:20

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 14:02:10

Generated On: 10 Jun 2021 10:01:20

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

What was the participant's randomization number? 184450

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 14:02:10

Generated On: 10 Jun 2021 10:01:20

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 14:02:10

Generated On: 10 Jun 2021 10:01:20

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 AUG 2020
Time of assessment (00:00-23:59)	10:41 (24 HR)
Vital Signs Date and Time (derived)	03 AUG 2020 10:41
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 14:02:10

Generated On: 10 Jun 2021 10:01:20

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 AUG 2020
Time of assessment (00:00-23:59)	12:02 (24 HR)
Vital Signs Date and Time (derived)	03 AUG 2020 12:02
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG



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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 14:02:10

Generated On: 10 Jun 2021 10:01:20

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 14:02:10

Generated On: 10 Jun 2021 10:01:20

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) 03 AUG 2020

What was the treatment time? (00:00-23:59) 11:32 (24 HR)

Treatment Date and Time (derived) 03 AUG 2020 11:32

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 14:02:10

Generated On: 10 Jun 2021 10:01:20

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

03 AUG 2020

Collection time (00:00-23:59)

11:16 (24 HR)

Collection date and time (derived)

03 AUG 2020 11:16

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 14:02:10

Generated On: 10 Jun 2021 10:01:20

Collection date (dd MMM yyyy)			03 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:15	03 AUG 2020 11:15
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:02:10

Generated On: 10 Jun 2021 10:01:20

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 10:01:20

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 AUG 2020 12:03

PC Open Date & Time

03 AUG 2020 11:52

PC Close Date & Time

03 AUG 2020 14:22

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

**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 93.6 °F

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

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

PC Time Stamp	03 AUG 2020 18:43
PC Open Date & Time	03 AUG 2020 15:17
PC Close Date & Time	04 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:01:20

**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

97.0 °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

04 AUG 2020 20:47

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

05 AUG 2020 19:03

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:01:20

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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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 19:30

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:01:20

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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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 05:59

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 18:11

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

09 AUG 2020 20:52

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

**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

03 AUG 2020 12:04

PC Open Date & Time

03 AUG 2020 11:52

PC Close Date & Time

03 AUG 2020 14:22

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

03 AUG 2020 18:44

PC Open Date & Time

03 AUG 2020 15:17

PC Close Date & Time

04 AUG 2020 11:59

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

6

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

04 AUG 2020 20:48

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59



US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

6

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

05 AUG 2020 19:03

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 AUG 2020 19:30

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:01:20

**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

08 AUG 2020 06:00

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:01:20

**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

08 AUG 2020 18:12

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 20:53

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

**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 ☐

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

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

No ☒

Yes ☐

PC Time stamp	03 AUG 2020 12:05
PC Open Date & Time	03 AUG 2020 11:52
PC Close Date & Time	03 AUG 2020 14:22

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

**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 ☐



US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

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

No ☒

Yes ☐

PC Time stamp	03 AUG 2020 18:44
PC Open Date & Time	03 AUG 2020 15:17
PC Close Date & Time	04 AUG 2020 11:59

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:01:20

**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 ☒

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:01:20

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 20:49
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:01:20

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 ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:01:20

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 19:04
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:01:20

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 ☒

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:01:20

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 19:31
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:01:20

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 ☒

PRODUCTION RELEASE (v12.003

55 of 2098

EAB) (1725)



US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:01:20

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 06:01
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:01:20

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 ☒

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:01:20

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 18:12
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:01:20

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 ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

59 of 2098

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:01:20

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 20:53
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3832055

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 14:02:09

Generated On: 10 Jun 2021 10:01:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3832055

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:02:09

Generated On: 10 Jun 2021 10:01:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832055

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 16:59:42

Generated On: 10 Jun 2021 10:01:20

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments LVM - CONTACT MADE AT 1715

*If Contact Not Made, please provide Comments*



US3832055

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 16:59:42

Generated On: 10 Jun 2021 10:01:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832055

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 16:59:42

Generated On: 10 Jun 2021 10:01:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3832055

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 16:59:42

Generated On: 10 Jun 2021 10:01:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832055

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 14:02:10

Generated On: 10 Jun 2021 10:01:20

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 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

US3832055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 14:02:20

Generated On: 10 Jun 2021 10:01:20

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)	09 SEP 2020
Time of assessment (00:00-23:59)	08:55 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 08:55
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)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3832055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 14:02:20

Generated On: 10 Jun 2021 10:01:20

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	09 SEP 2020
Time of assessment (00:00-23:59)	09:47 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 09:47
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3832055

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 14:02:10

Generated On: 10 Jun 2021 10:01:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 SEP 2020

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

US3832055

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 14:02:10

Generated On: 10 Jun 2021 10:01:20

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) 9 SEP 2020

What was the treatment time? (00:00-23:59) 09:17 (24 HR)

Treatment Date and Time (derived) 9 SEP 2020 09:17

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



US3832055

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 14:02:10

Generated On: 10 Jun 2021 10:01:20

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

9 SEP 2020

Collection time (00:00-23:59)

09:11 (24 HR)

Collection date and time (derived)

9 SEP 2020 09:11

US3832055

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 14:02:10

Generated On: 10 Jun 2021 10:01:20

Collection date (dd MMM yyyy)			9 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:07	9 SEP 2020 09:07
Nasopharyngeal Swab 2	No		

US3832055

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:02:10

Generated On: 10 Jun 2021 10:01:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

**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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 09:48

PC Open Date & Time

09 SEP 2020 09:37

PC Close Date & Time

09 SEP 2020 12:07

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.1 °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	09 SEP 2020 20:51
PC Open Date & Time	09 SEP 2020 13:02
PC Close Date & Time	10 SEP 2020 11:59

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:01:20

**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

97.1 °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

10 SEP 2020 19:48

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:01:20

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 19:29

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:01:20

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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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 19:17

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59



US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:01:20

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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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 19:16

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:01:20

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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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 19:15

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:01:20

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**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

97.2 °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

15 SEP 2020 20:23

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 09:49

PC Open Date & Time

09 SEP 2020 09:37

PC Close Date & Time

09 SEP 2020 12:07

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

**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

09 SEP 2020 20:53

PC Open Date & Time

09 SEP 2020 13:02

PC Close Date & Time

10 SEP 2020 11:59

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

75

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

10 SEP 2020 19:49

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

70

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

11 SEP 2020 19:31

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:01:20

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

50

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

12 SEP 2020 19:17

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59



US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:01:20

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

45

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

13 SEP 2020 19:17

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:01:20

**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

14 SEP 2020 19:16

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:01:20

**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

15 SEP 2020 20:23

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

**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 ☐

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 09:50
PC Open Date & Time	09 SEP 2020 09:37
PC Close Date & Time	09 SEP 2020 12:07

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

**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 ☐

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 20:53
PC Open Date & Time	09 SEP 2020 13:02
PC Close Date & Time	10 SEP 2020 11:59

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:01:20

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 ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:01:20

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 19:49
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:01:20

**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

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EAB) (1725)

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:01:20

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 19:32
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:01:20

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 19:18
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:01:20

**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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Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:01:20

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 19:17
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

DAY 6

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)



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Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:01:20

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 19:16
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:01:20

**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 ☒

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Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:01:20

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 20:24
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3832055

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 16:59:42

Generated On: 10 Jun 2021 10:01:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3832055

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 16:59:42

Generated On: 10 Jun 2021 10:01:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832055

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 14:02:09

Generated On: 10 Jun 2021 10:01:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3832055

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:02:09

Generated On: 10 Jun 2021 10:01:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832055

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 14:02:09

Generated On: 10 Jun 2021 10:01:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3832055

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:02:09

Generated On: 10 Jun 2021 10:01:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832055

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 14:02:21

Generated On: 10 Jun 2021 10:01:20

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 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

US3832055

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 14:02:21

Generated On: 10 Jun 2021 10:01:20

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	7 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	10:05 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 10:05
Temperature ( <i>xxx.x</i> )	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	66 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	160 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	87 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3832055

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 14:02:21

Generated On: 10 Jun 2021 10:01:20

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

7 OCT 2020

---

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

---

US3832055

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 14:02:21

Generated On: 10 Jun 2021 10:01:20

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

7 OCT 2020

Collection time (00:00-23:59)

10:20 (24 HR)

Collection date and time (derived)

7 OCT 2020 10:20

US3832055

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:02:21

Generated On: 10 Jun 2021 10:01:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 OCT 2020 10:06:37

Patient Cloud Open Date & Time

03 OCT 2020 00:01

Patient Cloud Close Date & Time

07 OCT 2020 23:59

US3832055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**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

11 OCT 2020 19:22:52

Patient Cloud Open Date & Time

10 OCT 2020 00:01

Patient Cloud Close Date & Time

14 OCT 2020 23:59



US3832055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 OCT 2020 08:59:20

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3832055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 OCT 2020 12:40:45
Patient Cloud Open Date & Time	31 OCT 2020 00:01
Patient Cloud Close Date & Time	04 NOV 2020 23:59

US3832055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 NOV 2020 08:13:58
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3832055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

DAY 106

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 17:50:04

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 NOV 2020 09:52:05

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**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

29 NOV 2020 14:40:51

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**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

06 DEC 2020 16:00:09

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**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

09 DEC 2020 17:31:54

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59



US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**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

16 DEC 2020 07:38:23

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 DEC 2020 10:59:39

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**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

30 DEC 2020 13:32:50

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**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

08 JAN 2021 17:19:58

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

<b>TIMEPOINT</b>	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 JAN 2021 11:47:38
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**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

20 JAN 2021 11:06:48

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 JAN 2021 08:00:25

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 FEB 2021 13:08:45

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59



US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 FEB 2021 08:32:14
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 FEB 2021 02:23:13

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 FEB 2021 16:53:01

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**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

04 MAR 2021 11:38:50

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

<b>TIMEPOINT</b>	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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 MAR 2021 10:39:37
Patient Cloud Open Date & Time	10 MAR 2021 00:01
Patient Cloud Close Date & Time	14 MAR 2021 23:59

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**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

17 MAR 2021 08:32:04

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 MAR 2021 11:49:56

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**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

31 MAR 2021 07:45:54

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59



US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**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

07 APR 2021 08:35:37

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 APR 2021 09:44:26

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 APR 2021 05:33:49

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

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

Date and time of submission

29 APR 2021 06:39:07

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**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 ☐

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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05 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

09 MAY 2021 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Open Date & Time](#)

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12 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAY 2021 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

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

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

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

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Open Date & Time](#)

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26 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAY 2021 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

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

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**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 ☐

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Open Date & Time](#)

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09 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 JUN 2021 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

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"/>

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Open Date & Time](#)

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16 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 JUN 2021 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

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

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

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	30 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 JUL 2021 23:59

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

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"/>

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Close Date & Time](#)

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11 JUL 2021 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

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"/>

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 JUL 2021 23:59

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**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 ☐

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**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 ☐

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Close Date & Time](#)

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01 AUG 2021 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**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 ☐

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Open Date & Time](#)

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04 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 AUG 2021 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**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 ☐

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**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 ☐

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	18 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	22 AUG 2021 23:59
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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

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

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**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°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 ☐

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

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

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

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°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"/>

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Close Date & Time](#)

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19 SEP 2021 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	22 SEP 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	26 SEP 2021 23:59
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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**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 ☐

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59



US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Close Date & Time](#)

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10 OCT 2021 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

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"/>

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Close Date & Time](#)

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17 OCT 2021 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

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"/>

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Open Date & Time](#)

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20 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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24 OCT 2021 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**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 ☐

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Open Date & Time](#)

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27 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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31 OCT 2021 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

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"/>

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Close Date & Time](#)

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07 NOV 2021 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**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 ☐

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	10 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	14 NOV 2021 23:59
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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**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 ☐

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

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"/>

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

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"/>

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**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 ☐

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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



US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

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"/>

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	29 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 JAN 2022 23:59

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Open Date & Time](#)

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05 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 JAN 2022 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

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"/>

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Open Date & Time](#)

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12 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 JAN 2022 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**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 ☐

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Close Date & Time](#)

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23 JAN 2022 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

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"/>

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Open Date & Time](#)

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26 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 JAN 2022 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**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 ☐

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Close Date & Time](#)

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06 FEB 2022 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**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 ☐

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Open Date & Time](#)

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09 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 FEB 2022 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**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 ☐

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59



US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**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 ☐

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**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 ☐

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Close Date & Time](#)

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06 MAR 2022 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

DAY 586

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Close Date & Time](#)

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20 MAR 2022 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

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"/>

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Open Date & Time](#)

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23 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAR 2022 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

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

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Open Date & Time](#)

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30 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 APR 2022 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

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"/>

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

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

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Open Date & Time](#)

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13 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 APR 2022 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Open Date & Time](#)

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20 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 APR 2022 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

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

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

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"/>

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Open Date & Time](#)

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04 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 MAY 2022 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

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

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

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Open Date & Time](#)

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11 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 MAY 2022 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

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"/>

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Close Date & Time](#)

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22 MAY 2022 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**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°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 ☐

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

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"/>

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Close Date & Time](#)

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05 JUN 2022 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**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 ☐

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**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 ☐

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Close Date & Time](#)

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19 JUN 2022 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

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"/>

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Open Date & Time](#)

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22 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 JUN 2022 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

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

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Open Date & Time](#)

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06 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 JUL 2022 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

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"/>

US3832055

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Close Date & Time](#)

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17 JUL 2022 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

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

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

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

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Open Date & Time](#)

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27 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 JUL 2022 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

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"/>

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Open Date & Time](#)

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03 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 AUG 2022 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

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"/>

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	10 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	14 AUG 2022 23:59
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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

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"/>

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Open Date & Time](#)

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17 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 AUG 2022 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**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 ☐

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	24 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	28 AUG 2022 23:59
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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

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 ☐

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Open Date & Time](#)

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31 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 SEP 2022 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

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="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"/>

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Close Date & Time](#)

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11 SEP 2022 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

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 <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"/>

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

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[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

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 <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"/>

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 SEP 2022 23:59

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**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 ☐

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

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

28 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

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US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

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"/>

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	05 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	09 OCT 2022 23:59
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US3832055

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 10:01:20

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		04 MAR 2021 11:39:02

US3832055

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 16:59:42

Generated On: 10 Jun 2021 10:01:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3832055

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 16:59:42

Generated On: 10 Jun 2021 10:01:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832055

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 16:59:41

Generated On: 10 Jun 2021 10:01:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3832055

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 16:59:41

Generated On: 10 Jun 2021 10:01:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832055

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 16:59:42

Generated On: 10 Jun 2021 10:01:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3832055

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 16:59:42

Generated On: 10 Jun 2021 10:01:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832055

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 16:59:42

Generated On: 10 Jun 2021 10:01:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3832055

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 16:59:42

Generated On: 10 Jun 2021 10:01:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832055

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 23:02:12

Generated On: 10 Jun 2021 10:01:20

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

Visit date (dd MMM yyyy)	22 MAR 2021
--------------------------	-------------

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

Folder OID	VISIT4
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US3832055

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 23:02:12

Generated On: 10 Jun 2021 10:01:20

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) \_\_\_\_\_

US3832055

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 23:02:12

Generated On: 10 Jun 2021 10:01:20

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.*

US3832055

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 23:02:12

Generated On: 10 Jun 2021 10:01:20

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 MAR 2021

Collection time (00:00-23:59)

09:10 (24 HR)

Collection date and time (derived)

22 MAR 2021 09:10

US3832055

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 23:02:12

Generated On: 10 Jun 2021 10:01:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3832055

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 23:02:12

Generated On: 10 Jun 2021 10:01:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3832055

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 23:02:12

Generated On: 10 Jun 2021 10:01:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832055

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

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*

**US3832055**

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

**Form: Continuing**

**Generated On: 10 Jun 2021 10:01:20**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3832055

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:01:20

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"/>

**US3832055**

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

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

**Generated On: 10 Jun 2021 10:01:20**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3832055

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

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 16:59:41

Generated On: 10 Jun 2021 10:01:20

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 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

US3832055

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

Form: Unblinding

Data signed: (b) (4) 12 Apr 2021 23:02:12

Generated On: 10 Jun 2021 10:01:20

Date of updated informed consent (dd MMM yyyy) 4 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) 4 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 \_\_\_\_\_



US3832055

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 16:59:41

Generated On: 10 Jun 2021 10:01:20

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

4 JAN 2021

Collection time (00:00-23:59)

13:00 (24 HR)

Collection date and time (derived)

4 JAN 2021 13:00

US3832055

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 21 Feb 2021 16:59:41

Generated On: 10 Jun 2021 10:01:20

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 JAN 2021
Collection time (00:00 - 23:59)	13:00
Collection Date and Time (derived)	4 JAN 2021 13:00

US3832055

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 21 Feb 2021 16:59:41

Generated On: 10 Jun 2021 10:01:20

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3832055

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 21 Feb 2021 16:59:41

Generated On: 10 Jun 2021 10:01:20

AEID	USA-US100-2020-MRNA-1273-P30 1000004
Adverse event	SYNCPAL EPISODE
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)	20 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	23 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	20 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	23 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3832055

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 21 Feb 2021 16:59:41

Generated On: 10 Jun 2021 10:01:20

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	

US3832055

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 21 Feb 2021 16:59:41

Generated On: 10 Jun 2021 10:01:20

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71 Y/O RANDOMIZED MALE  
WHO RECEIVED THE FIRST  
DOSE OF BLINDED MRNA-1273  
OR PLACEBO FOR SARS-COV-2  
VACCINATION ON 8/3/2020 AND  
HIS SECOND, FINAL DOSE OF  
STUDY DRUG, ON 09/09 2020.  
PRESENTED TO THE ER ON  
9/20/2020 AFTER A SYNCOPE  
EPISODE AND FALL. A CT OF  
THE FACIAL BONES WAS  
COMPLETED WITH THE  
FOLLOWING FINDINGS  
FRACTURE OF THE MEDIAL  
AND LATERAL RIGHT ORBITAL  
WALL THE ORBITAL FLOOR  
AND THE  
ANTERIOR/POSTERIOR  
MAXILLARY SINUS WALLS.  
NONDISPLACED ZYGOMATIC  
ARCH FRACTURE AND RIGHT  
PERIORBITAL SOFT TISSUE  
SWELLING AND HEMATOMA. A  
CT OF THE HEAD AND SPINE  
COMPLETED NOTED WITHIN  
NORMAL LIMITS. EKG  
COMPLETED NOTED WNL.  
ADMISSION DIAGNOSES  
INCLUDE: SYNCOPE AND  
COLLAPSE, CLOSED FRACTURE  
OF LATERAL WALL OF THE  
RIGHT ORBIT AND  
HYPONATREMIA CHLORIDE  
LEVELS:  
9/22/2020: 91

US3832055

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 21 Feb 2021 16:59:41

Generated On: 10 Jun 2021 10:01:20

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	MMOL/L
	9/21/2020: 91MMOL/L
	9/20/2020: 90MMOL/L
	REFERENCE RANGE
	98-107MMOL/L
	SUBJECT WAS SCHEDULED FOR
	OPEN REDUCTION, INTERNAL
	FIXATION OF THE RIGHT
	ZYGOMATICOMAXILLARY
	COMPLEX FRACTURE.
	SUBJECT WAS SWITCHED
	FROM NORVASC TO
	LISINOPRIL AND TOLD TO
	CONTINUE BYSTOLIC
	DISCHARGED 09/23/2020
	NEW MEDICATIONS
	LISINOPRIL 5MG 9/24/2020 1 PO
	QD
	SODIUM CHLORIDE 1G TABLET
	PO TID
	OXYCODONE-ACETAMINOPHE
	N 7.5-325MG Q 4-6 HRS PRN

---

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

---

US3832055

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 21 Feb 2021 16:59:41

Generated On: 10 Jun 2021 10:01:20

AEID

Adverse event

CLOSED FRACTURE OF  
LATERAL WALL OF THE RIGHT  
ORBIT

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

20 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

23 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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EAB) (1725)



US3832055

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 21 Feb 2021 16:59:41

Generated On: 10 Jun 2021 10:01:20

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	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3832055

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 21 Feb 2021 16:59:41

Generated On: 10 Jun 2021 10:01:20

AEID

Adverse event

HYPONATREMIA

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

20 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

23 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

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Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related ☒  
Related ☐  
Not Applicable ☐

Relationship to Study Procedure Not Related ☒  
Related ☐  
Not Applicable ☐

Action taken with investigational product None ☐  
Dose Delayed ☐  
Investigational Product ☐  
Withdrawn ☐  
Not Applicable ☒

Other action taken (check all that apply)

None False

Concomitant Medication True

Concomitant Procedure False

Outcome Fatal ☐  
Not Recovered/Not Resolved ☐  
Recovered/Resolved ☐  
Recovered/Resolved with Sequelae ☒  
Recovering/Resolving ☐  
Unknown ☐

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

SUBJECT WAS HOSPITALIZED FOR A SYNCOPIAL EPISODE 20-23 SEP 2020. DURING HOSPITALIZATION, SUBJECT WAS GIVEN A DOSE OF SAMSCA TO CORRECT SODIUM LEVELS. SUBJECT D/C WITH SODIUM CHLORIDE RX. STABLE AT D/C

Narrative

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Folder: Adverse Events

Form: Adverse Events (3)

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

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

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

**Data signed:** (b) (4) 21 Feb 2021 16:59:41

**Generated On: 10 Jun 2021 10:01:20**

---

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

Yes ☒

No ☐

---

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

---

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 21 Feb 2021 16:59:41

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Name of Medication OXYCODONE

Prophylaxis Yes ☒  
No ☐

Indication DEGENERATIVE DISC DISEASE

Dose per administration 325/7.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 21 Feb 2021 16:59:41

Generated On: 10 Jun 2021 10:01:20

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 21 Feb 2021 16:59:41

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Name of Medication NATURE THROID

Prophylaxis Yes ☐  
No ☒

Indication HYPOTHYROIDISM

Dose per administration 130

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) 21 Feb 2021 16:59:41

Generated On: 10 Jun 2021 10:01:20

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 21 Feb 2021 16:59:41

Generated On: 10 Jun 2021 10:01:20

Name of Medication AMLODIPINE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

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 (3)

Data signed: (b) (4) 21 Feb 2021 16:59:41

Generated On: 10 Jun 2021 10:01:20

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	20 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 21 Feb 2021 16:59:41

Generated On: 10 Jun 2021 10:01:20

Name of Medication FLUTICASONE PROPINATE

Prophylaxis Yes ☐  
No ☒

Indication ALLERGIC RHINITIS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 21 Feb 2021 16:59:41

Generated On: 10 Jun 2021 10:01:20

	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)	UN UNK 2000	
Start date completely unknown	False	
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) 21 Feb 2021 16:59:41

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Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication VACCINATION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 21 Feb 2021 16:59:41

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	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)	25 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		25 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 21 Feb 2021 16:59:41

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Name of Medication BYSTOLIC

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 21 Feb 2021 16:59:41

Generated On: 10 Jun 2021 10:01:20

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 21 Feb 2021 16:59:41

Generated On: 10 Jun 2021 10:01:20

Name of Medication LISINOPRIL

Prophylaxis Yes ☐  
No ☒

Indication AE-SYNCPAL EPISODE

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 21 Feb 2021 16:59:41

Generated On: 10 Jun 2021 10:01:20

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 21 Feb 2021 16:59:41

Generated On: 10 Jun 2021 10:01:20

Name of Medication SODIUM CHLORIDE

Prophylaxis Yes ☐  
No ☒

Indication AE-HYPONATREMIA

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 (8)

Data signed: (b) (4) 21 Feb 2021 16:59:41

Generated On: 10 Jun 2021 10:01:20

	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)		24 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)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 21 Feb 2021 16:59:41

Generated On: 10 Jun 2021 10:01:20

Name of Medication SAMSCA

Prophylaxis Yes ☐  
No ☒

Indication AE- HYPONATREMIA

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 21 Feb 2021 16:59:41

Generated On: 10 Jun 2021 10:01:20

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 21 Feb 2021 16:59:41

Generated On: 10 Jun 2021 10:01:20

Name of Medication OXYCODONE-ACETAMINOPHE  
N (7.5MG-325MG)

Prophylaxis Yes ☐  
No ☒

Indication POST SURGICAL PAIN

Dose per administration 2

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

EVERY 4-6 HOURS AS NEEDED

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 21 Feb 2021 16:59:41

Generated On: 10 Jun 2021 10:01:20

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		21 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3832055

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 21 Feb 2021 16:59:41

Generated On: 10 Jun 2021 10:01:20

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

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US3832055

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 08 Mar 2021 12:06:26

Generated On: 10 Jun 2021 10:01:20

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
22 SEP 2020	OPEN REDUCTION, INTERNAL FIXATION OF THE RIGHT ZYGOMATICOMAXILLARY COMPLEX FRACTURE.	Adverse Event	
20 SEP 2020	CT OF FACIAL BONES	Adverse Event	
20 SEP 2020	HYPONATREMIA CHLORIDE LEVELS	Adverse Event	
21 SEP 2020	HYPONATREMIA CHLORIDE LEVELS	Adverse Event	
22 SEP 2020	HYPONATREMIA CHLORIDE LEVELS	Adverse Event	
20 AUG 2020	EKG	Adverse Event	
20 AUG 2020	CT SCAN OF NECK AND SPINE	Adverse Event	

US3832055

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:01:20

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 21 Feb 2021 16:59:41

Generated On: 10 Jun 2021 10:01:20

SAEID	USA-US100-2020-MRNA-1273-P301000004
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	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 21 Feb 2021 16:59:41

Generated On: 10 Jun 2021 10:01:20

SAEID	USA-US100-2020-MRNA-1273-P301000004
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	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	23/SEP/2020 21:59
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

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 21 Feb 2021 16:59:41

Generated On: 10 Jun 2021 10:01:20

SAEID	USA-US100-2020-MRNA-1273-P301000004
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	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	24/SEP/2020 14:12
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

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 21 Feb 2021 16:59:41

Generated On: 10 Jun 2021 10:01:20

SAEID	USA-US100-2020-MRNA-1273-P301000004
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	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	12/NOV/2020 10:16
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Data signed: (b) (4) 21 Feb 2021 16:59:41

Generated On: 10 Jun 2021 10:01:20

SAEID	USA-US100-2020-MRNA-1273-P301000004
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	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	04/DEC/2020 14:10
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

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Data signed: (b) (4) 21 Feb 2021 16:59:41

Generated On: 10 Jun 2021 10:01:20

SAEID	USA-US100-2020-MRNA-1273-P301000004
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	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	04/DEC/2020 17:41
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

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Data signed: (b) (4) 21 Feb 2021 16:59:41

Generated On: 10 Jun 2021 10:01:20

SAEID	USA-US100-2020-MRNA-1273-P301000004
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	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	10/FEB/2021 09:20
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3832055 (Prod: Keystone VitaLink Research - Anderson - PPDS)

US3832055

Form: Participant Creation

Generated On: 10 Jun 2021 10:01:20

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'US3832055'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 14:29:35

US3832055

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:01:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:20:42
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:33
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:18:08
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:10:55

US3832055

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:20:42
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:33
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:18:08
User entered '03 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 14:29:35

US3832055

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:01:20

[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 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:20:42
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:33
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:18:08
User entered 'Clinic (Clinic)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:10:55



US3832055

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:01:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered 'SCRN'	System	03 Aug 2020 15:10:55

US3832055

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:01:20

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:21:14
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:18:29
User entered (b) (6) 1949'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 14:29:36

US3832055

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:01:20

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:21:14
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:18:34
User entered '71'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:11:25

US3832055

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:01:20

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered 'YEARS'	System	03 Aug 2020 15:11:25

US3832055

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:01:20

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered '71'	System	03 Aug 2020 15:11:42

US3832055

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:01:20

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:21:14
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:18:35
User entered 'Male (M)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:15:19
User entered 'Female (F)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:11:25

US3832055

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:01:20

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:21:14
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:18:41
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:11:25

US3832055

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:01:20

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:21:14
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:18:42
User entered 'I'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:11:25



US3832055

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:01:20

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:21:14
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:18:46
User entered '0'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:11:25

US3832055

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:01:20

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:21:14
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:18:46
User entered '0'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:11:25

US3832055

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:01:20

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:21:14
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:18:46
User entered '0'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:11:25

US3832055

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:01:20

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:21:14
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:18:46
User entered '0'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:11:25

US3832055

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:01:20

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:21:14
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:18:46
User entered '0'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:11:25

US3832055

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:01:20

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:21:14
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:18:46
User entered empty.	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:11:25

US3832055

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:01:20

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:21:14
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:18:46
User entered '0'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:11:25

US3832055

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:01:20

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:21:14
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:18:46
User entered '0'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:11:25



US3832055

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:01:20

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 13:52:09
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:40
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:19:52
User entered '03 Aug 2020'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:11:42

US3832055

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered 'Aug 2020'	System	03 Aug 2020 15:11:42

US3832055

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered '2020'	System	03 Aug 2020 15:11:42

US3832055

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:01:20

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 13:52:09
Query 'Per the source in CRIO, subject was reconsented. Please review and reconcile.' canceled (Site from CRA).	(b) (4), (b) (6)	13 Oct 2020 13:52:05
User opened query 'Per the source in CRIO, subject was reconsented. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	13 Oct 2020 13:43:35
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:40
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:19:52
User entered 'Amendment 1 (1)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:11:42

US3832055

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 13:52:09
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:40
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:19:52
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:11:42

US3832055

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:01:20

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 13:52:09
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:40
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:19:52
User entered empty.	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:11:42

US3832055

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:01:20

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 13:52:09
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:40
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:19:52
User entered empty.	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:11:42

US3832055

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:01:20

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 13:52:09
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:40
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:19:52
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:11:42



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Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:01:20

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	13 Oct 2020 13:52:09
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:40
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:19:52
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 14:29:35

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Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:01:20

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered 'I'	System	03 Aug 2020 15:11:49

US3832055

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:21:27
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:45
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:20:41
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:11:49

US3832055

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:01:20

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:21:40
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:49
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:21:02
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:11:59

US3832055

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:01:20

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:22:03
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:54
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:23:40
User coded data point as SOC: Vascular disorders, HLG: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 15:13:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 15:13:01
Data point term sent to Coder	System	03 Aug 2020 15:12:40
User entered 'Hypertension'	Alyssa-Kay Peay (b) (4) (b) (4)	03 Aug 2020 15:12:16

US3832055

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:01:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:03
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:54
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:23:40
User entered 'un UNK 2015'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:12:16

US3832055

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:01:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:03
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:54
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:23:40
User entered '0'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:12:16

US3832055

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:01:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:03
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:54
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:23:40
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:12:16



US3832055

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:01:20

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:03
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:54
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:23:40
User entered empty.	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:12:16

US3832055

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:01:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:03
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:54
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:23:40
User entered '0'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:12:16

US3832055

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:01:20

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered 'Jan 2015'	System	03 Aug 2020 15:12:16

US3832055

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:01:20

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered '2015'	System	03 Aug 2020 15:12:16

US3832055

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered empty.	System	03 Aug 2020 15:12:16

US3832055

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered empty.	System	03 Aug 2020 15:12:16

US3832055

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:01:20

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:22:03
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:54
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:23:40
User coded data point as SOC: Endocrine disorders, HLG: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 15:13:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 15:13:01
Data point term sent to Coder	System	03 Aug 2020 15:12:41
User entered 'Hypothyroidism'	Alyssa-Kay Peay (b) (4) (b) (4)	03 Aug 2020 15:12:38

US3832055

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:03
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:54
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:23:40
User entered 'un UNK 2015'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:12:38



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Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:01:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:03
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:54
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:23:40
User entered '0'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:12:38

US3832055

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:01:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:03
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:54
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:23:40
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:12:38

US3832055

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:01:20

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:03
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:54
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:23:40
User entered empty.	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:12:38

US3832055

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:01:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:03
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:54
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:23:40
User entered '0'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:12:38

US3832055

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:01:20

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered 'Jan 2015'	System	03 Aug 2020 15:12:38

US3832055

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:01:20

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered '2015'	System	03 Aug 2020 15:12:38

US3832055

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered empty.	System	03 Aug 2020 15:12:38

US3832055

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered empty.	System	03 Aug 2020 15:12:38



US3832055

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:01:20

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:22:03
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:54
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:23:40
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc degeneration, LLT: Degenerative disc disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 15:15:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 15:15:04
Data point term sent to Coder	System	03 Aug 2020 15:13:41
User entered 'Degenerative Disc Disease'	Alyssa-Kay Peay (b) (4) (b) (4)	03 Aug 2020 15:12:58

US3832055

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:03
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:54
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:23:40
User entered 'un UNK 1999'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:12:58

US3832055

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:01:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:03
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:54
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:23:40
User entered '0'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:12:58

US3832055

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:01:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:03
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:54
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:23:40
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:12:58

US3832055

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:01:20

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:03
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:54
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:23:40
User entered empty.	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:12:58

US3832055

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:01:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:03
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:05:54
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:23:40
User entered '0'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:12:58

US3832055

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered 'Jan 1999'	System	03 Aug 2020 15:12:58

US3832055

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:01:20

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered '1999'	System	03 Aug 2020 15:12:58



US3832055

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered empty.	System	03 Aug 2020 15:12:58

US3832055

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered empty.	System	03 Aug 2020 15:12:58

US3832055

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:01:20

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 20:06:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 20:06:41
Data point term sent to Coder	System	28 Oct 2020 20:36:49
User entered 'Cholecystitis'	Alyssa-Kay Peay (b) (4)	28 Oct 2020 20:36:46

US3832055

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User entered 'UN May 2019'	Alyssa-Kay Peay (b) (4)	28 Oct 2020 20:36:46

US3832055

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:01:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User entered '0'	Alyssa-Kay Peay (b) (4)	28 Oct 2020 20:36:46

US3832055

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:01:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	28 Oct 2020 20:36:46

US3832055

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:01:20

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User entered 'UN May 2019'	Alyssa-Kay Peay (b) (4)	28 Oct 2020 20:36:46

US3832055

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:01:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User entered '0'	Alyssa-Kay Peay (b) (4)	28 Oct 2020 20:36:46



US3832055

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered 'May 2019'	System	28 Oct 2020 20:36:46

US3832055

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered '2019'	System	28 Oct 2020 20:36:46

US3832055

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered 'May 2019'	System	28 Oct 2020 20:36:46

US3832055

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered '2019'	System	28 Oct 2020 20:36:46

US3832055

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:01:20

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Rhinitis allergic, LLT: Allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 20:06:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 20:06:46
Data point term sent to Coder	System	28 Oct 2020 20:38:50
User entered 'Allergic Rhinitis'	Alyssa-Kay Peay (b) (4)	28 Oct 2020 20:38:04

US3832055

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User entered 'UN UNK 2000'	Alyssa-Kay Peay (b) (4)	28 Oct 2020 20:38:04

US3832055

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:01:20

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User entered '0'	Alyssa-Kay Peay (b) (4)	28 Oct 2020 20:38:04

US3832055

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:01:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	28 Oct 2020 20:38:04



US3832055

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:01:20

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User entered empty.	Alyssa-Kay Peay (b) (4)	28 Oct 2020 20:38:04

US3832055

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:01:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User entered '0'	Alyssa-Kay Peay (b) (4)	28 Oct 2020 20:38:04

US3832055

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered 'Jan 2000'	System	28 Oct 2020 20:38:04

US3832055

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered '2000'	System	28 Oct 2020 20:38:04

US3832055

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered empty.	System	28 Oct 2020 20:38:04

US3832055

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered empty.	System	28 Oct 2020 20:38:04

US3832055

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:01:20

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Intermittent headache - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 20:06:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 20:06:46
Data point term sent to Coder	System	28 Oct 2020 20:38:52
User entered 'Intermittent Headaches'	Alyssa-Kay Peay (b) (4)	28 Oct 2020 20:38:38

US3832055

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User entered 'UN UNK 1990'	Alyssa-Kay Peay (b) (4)	28 Oct 2020 20:38:38



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Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:01:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User entered '0'	Alyssa-Kay Peay (b) (4)	28 Oct 2020 20:38:38

US3832055

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:01:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	28 Oct 2020 20:38:38

US3832055

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:01:20

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User entered empty.	Alyssa-Kay Peay (b) (4)	28 Oct 2020 20:38:38

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Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:01:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User entered '0'	Alyssa-Kay Peay (b) (4)	28 Oct 2020 20:38:38

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Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered 'Jan 1990'	System	28 Oct 2020 20:38:38

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Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:01:20

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered '1990'	System	28 Oct 2020 20:38:38

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Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered empty.	System	28 Oct 2020 20:38:38

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Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered empty.	System	28 Oct 2020 20:38:38



US3832055

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:01:20

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:02:12
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Paranasal sinus disorders (excl infections and neoplasms), PT: Paranasal cyst, LLT: Maxillary sinus cyst - version MedDRA\23.0.	Coder Import (b) (4)	15 Mar 2021 09:33:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	15 Mar 2021 09:33:54
Data point term sent to Coder	System	11 Mar 2021 20:11:04
User closed query 'CDM-Coding: Please clarify this clinical event with more details if it is 1. Maxillary sinus cyst Or Something else and amend /update the term accordingly in the diagnosis field to enable coding.	System	11 Mar 2021 20:10:15
' (Site from System).		
Query 'CDM-Coding: Please clarify this clinical event with more details if it is 1. Maxillary sinus cyst Or Something else and amend /update the term accordingly in the diagnosis field to enable coding.	Danyel Johnson (b) (4)	11 Mar 2021 20:10:15
' answered with 'Updated per subject report' (Site from System).	(b) (4)	
Data point term sent to Coder	System	11 Mar 2021 20:09:01
Signature has been broken.	Danyel Johnson (b) (4)	11 Mar 2021 20:08:39
User entered 'Maxillary sinus cyst (BENIGN)' reason for change: Data Entry Error	(b) (4)	
User opened query 'CDM-Coding: Please clarify this clinical event with more details if it is 1. Maxillary sinus cyst Or Something else and amend /update the term accordingly in the diagnosis field to enable coding.	Danyel Johnson (b) (4)	11 Mar 2021 20:08:39
' (Site from System).	(b) (4)	
User signature succeeded.	Coder Import (b) (4)	09 Mar 2021 13:58:56
	(b) (4)	
	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
	(b) (4)	

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Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:01:20

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the condition to confirm if the SINUS CYST was benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 07:07:10
Query 'Per DM CLR: Please update the condition to confirm if the SINUS CYST was benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	Danyel Johnson (b) (4)	26 Jan 2021 20:12:34
' answered with 'Review and updated' (Site from DM).	(b) (4)	
Data point term sent to Coder	System	26 Jan 2021 20:12:26
Coding entries removed.	Danyel Johnson (b) (4)	26 Jan 2021 20:12:23
	(b) (4)	
User entered 'SINUS CYST (Benign)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	26 Jan 2021 20:12:23
	(b) (4)	
User opened query 'Per DM CLR: Please update the condition to confirm if the SINUS CYST was benign or cancerous. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	15 Jan 2021 02:31:47
' (Site from DM).		
User coded data point as SOC: General disorders and administration site conditions, HLGT: Tissue disorders NEC, HLT: Mass conditions NEC, PT: Cyst, LLT: Cyst - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 20:06:51
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Oct 2020 20:06:51
	(b) (4)	
Data point term sent to Coder	System	28 Oct 2020 20:39:53
User entered 'Sinus Cyst'	Alyssa-Kay Peay (b) (4)	28 Oct 2020 20:39:17
	(b) (4)	

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Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User entered 'UN UNK 2019'	Alyssa-Kay Peay (b) (4)	28 Oct 2020 20:39:17

US3832055

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:01:20

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User entered '0'	Alyssa-Kay Peay (b) (4)	28 Oct 2020 20:39:17

US3832055

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:01:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	28 Oct 2020 20:39:17

US3832055

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:01:20

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User entered 'UN Dec 2019'	Alyssa-Kay Peay (b) (4)	28 Oct 2020 20:39:17

US3832055

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:01:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User entered '0'	Alyssa-Kay Peay (b) (4)	28 Oct 2020 20:39:17

US3832055

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered 'Jan 2019'	System	28 Oct 2020 20:39:17



US3832055

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:01:20

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered '2019'	System	28 Oct 2020 20:39:17

US3832055

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered 'Dec 2019'	System	28 Oct 2020 20:39:17

US3832055

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered '2019'	System	28 Oct 2020 20:39:17

US3832055

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:01:20

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal disorders NEC, PT: Nasal septum deviation, LLT: Deviated nasal septum - version MedDRA\23.0.	Coder Import (b) (4)	29 Oct 2020 20:07:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	29 Oct 2020 20:07:13
Data point term sent to Coder	System	28 Oct 2020 20:40:54
User entered 'Deviated Septum'	Alyssa-Kay Peay (b) (4)	28 Oct 2020 20:40:04

US3832055

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User entered 'UN UNK 2018'	Alyssa-Kay Peay (b) (4)	28 Oct 2020 20:40:04

US3832055

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:01:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User entered '0'	Alyssa-Kay Peay (b) (4)	28 Oct 2020 20:40:04

US3832055

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:01:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	28 Oct 2020 20:40:04

US3832055

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:01:20

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User entered 'UN Dec 2019'	Alyssa-Kay Peay (b) (4)	28 Oct 2020 20:40:04



US3832055

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:01:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User entered '0'	Alyssa-Kay Peay (b) (4)	28 Oct 2020 20:40:04

US3832055

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered 'Jan 2018'	System	28 Oct 2020 20:40:04

US3832055

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:01:20

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered '2018'	System	28 Oct 2020 20:40:04

US3832055

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered 'Dec 2019'	System	28 Oct 2020 20:40:04

US3832055

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered '2019'	System	28 Oct 2020 20:40:04

US3832055

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:56
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:14:38

US3832055

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:56
User entered '03 Aug 2020'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:14:38

US3832055

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:56
User entered '10:41'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:14:38



US3832055

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered '03 Aug 2020 10:41'	System	03 Aug 2020 15:14:38

US3832055

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:56
User entered '67' in	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:14:38
DataPoint set to visible.	System	03 Aug 2020 15:11:49

US3832055

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:56
User entered '190' lb	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:14:38
DataPoint set to visible.	System	03 Aug 2020 15:11:49

US3832055

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
Amendment Manager: User entered '29.82043'	System	16 Sep 2020 23:41:02
User entered '29.8'	System	03 Aug 2020 15:14:38
DataPoint set to visible.	System	03 Aug 2020 15:11:49

US3832055

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered 'kg/m2'	System	03 Aug 2020 15:14:38
DataPoint set to visible.	System	03 Aug 2020 15:11:49

US3832055

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User closed query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:43:04
Query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1.	Danyel Johnson (b) (4)	03 Nov 2020 16:57:01
' answered with 'Update per query ' (Site from CRA).	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4)	03 Nov 2020 16:56:55
User opened query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	02 Nov 2020 23:46:20
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 23:45:46
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:56
User entered '98.2' F	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:14:38
	(b) (4)	

US3832055

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User closed query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:43:06
Query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1' answered with 'Update per query' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 16:57:06
User entered empty; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 16:56:55
User opened query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1' (Site from CRA).	(b) (4), (b) (6)	02 Nov 2020 23:46:34
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 23:45:48
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:56
User entered 'Oral (Oral)'	Alyssa-Kay Peay (b) (4) (b) (4)	03 Aug 2020 15:14:38

US3832055

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User closed query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:43:07
Query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1' answered with 'Update per query ' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 16:57:12
User opened query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1' (Site from CRA).	(b) (4), (b) (6)	02 Nov 2020 23:46:42
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 23:45:49
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:56
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	03 Aug 2020 15:14:38



US3832055

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User closed query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:43:09
Query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1' answered with 'Update per query' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 16:57:17
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 16:56:55
User opened query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1' (Site from CRA).	(b) (4), (b) (6)	02 Nov 2020 23:46:52
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 23:45:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:56
User entered '78'	Alyssa-Kay Peay (b) (4) (b) (4)	03 Aug 2020 15:14:38

US3832055

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered 'bpm'	System	03 Aug 2020 15:14:38

US3832055

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User closed query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:43:10
Query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1' answered with 'Update per query' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 16:57:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 16:56:55
User opened query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1' (Site from CRA).	(b) (4), (b) (6)	02 Nov 2020 23:47:07
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 23:45:52
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:56
User entered '16'	Alyssa-Kay Peay (b) (4) (b) (4)	03 Aug 2020 15:14:38

US3832055

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered 'breaths/min'	System	03 Aug 2020 15:14:38

US3832055

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User closed query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:43:11
Query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1' answered with 'Update per query' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 16:57:28
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 16:56:55
User opened query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1' (Site from CRA).	(b) (4), (b) (6)	02 Nov 2020 23:47:14
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 23:45:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:56
User entered '146'	Alyssa-Kay Peay (b) (4) (b) (4)	03 Aug 2020 15:14:38

US3832055

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered 'mmHg'	System	03 Aug 2020 15:14:38

US3832055

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User closed query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:43:13
Query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1' answered with 'Update per query' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 16:57:33
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 16:56:55
User opened query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1' (Site from CRA).	(b) (4), (b) (6)	02 Nov 2020 23:47:22
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 23:45:55
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:22:56
User entered '74'	Alyssa-Kay Peay (b) (4) (b) (4)	03 Aug 2020 15:14:38

US3832055

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered 'mmHg'	System	03 Aug 2020 15:14:38



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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42

US3832055

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:01:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:23:04
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:14:49

US3832055

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:01:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:23:04
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 15:03:18
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		09 Sep 2020 13:22:25
User entered '03 Aug 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	03 Aug 2020 15:14:49

US3832055

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:01:20

**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 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:24:55
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:10
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:24:51
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:16:09

US3832055

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:01:20

**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 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:24:55
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:10
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:24:51
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:16:09

US3832055

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:01:20

**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 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:24:55
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:10
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:24:51
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:16:09

US3832055

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:01:20

**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 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:24:55
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:10
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:24:51
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:16:09



US3832055

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:01:20

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 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:24:55
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:10
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:24:51
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:16:09

US3832055

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:01:20

[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 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:24:55
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:10
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:24:51
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:16:09

US3832055

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:01:20

**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 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:24:55
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:10
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:24:51
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:16:09

US3832055

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:01:20

**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 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:24:55
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:10
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:24:51
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:16:09

US3832055

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:01:20

[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 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:24:55
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:10
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:24:51
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:16:09

US3832055

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:01:20

**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 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:24:55
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:10
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:24:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:16:09

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:01:20

**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 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:24:55
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:10
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:24:40
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:16:09

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Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User closed query 'please delete' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 12:17:04
Query 'Data is required. Please complete.' answered with 'Update per query' (Site from System).	(b) (4), (b) (6)	05 Nov 2020 16:43:20
Query 'please delete' answered with 'Update per query' (Site from CRA).	(b) (4), (b) (6)	
User opened query 'Data is required. Please complete.' (Site from System).	Danyel Johnson (b) (4)	03 Nov 2020 16:54:51
User entered empty; reason for change Data Entry Error	(b) (4)	
User opened query 'please delete' (Site from CRA).	Danyel Johnson (b) (4)	03 Nov 2020 16:54:46
DataPoint Un-verified.	(b) (4)	
DataPoint Verified.	System	03 Nov 2020 16:54:39
DataPoint Un-verified.	Danyel Johnson (b) (4)	03 Nov 2020 16:54:39
DataPoint Verified.	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Nov 2020 23:51:04
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	02 Nov 2020 23:48:37
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	27 Oct 2020 20:24:55
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	01 Oct 2020 02:06:10
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	29 Sep 2020 18:24:38
	(b) (4), (b) (6)	
	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:16:09
	(b) (4)	



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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User closed query 'This section is for living conditions. please delete this' (Site from CRA).	(b) (4)	
Query 'This section is for living conditions. please delete this' answered with 'Update per query ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:43:25
User entered empty; reason for change Data Entry Error	Danyel Johnson (b) (4)	03 Nov 2020 16:54:57
User opened query 'This section is for living conditions. please delete this' (Site from CRA).	(b) (4)	
DataPoint Un-verified.	Danyel Johnson (b) (4)	03 Nov 2020 16:54:39
DataPoint Verified.	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 23:51:30
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 23:48:39
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 20:24:55
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:10
User entered '71 yo'	(b) (4), (b) (6)	29 Sep 2020 18:24:51
	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:16:09
	(b) (4)	

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User closed query 'please remove checked box If none of the selections are applicable, select 'other' and specify (ie homeless)' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 16:43:54
Query 'please remove checked box If none of the selections are applicable, select 'other' and specify (ie homeless)' answered with 'Update per query ' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 16:55:09
User closed query "No Risk Identified' is not checked, however no other risks are selected. Please review and reconcile.' (Site from System).	System	03 Nov 2020 16:55:04
User entered '1' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 16:55:04
User opened query "No Risk Identified' is not checked, however no other risks are selected. Please review and reconcile.' (Site from System).	System	03 Nov 2020 16:54:39
User entered '0' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 16:54:39
User opened query 'please remove checked box If none of the selections are applicable, select 'other' and specify (ie homeless)' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 00:01:29
User entered '1'	Alyssa-Kay Peay (b) (4) (b) (4)	03 Aug 2020 15:16:09

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[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:24:55
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:10
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:24:51
User entered '0'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:16:09

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**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 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:24:55
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:10
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:24:51
User entered '0'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:16:09

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Form: Risk of Exposure

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[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 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:24:55
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:10
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:24:51
User entered '0'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:16:09

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Folder: Screening

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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 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:24:55
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:10
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:24:51
User entered '0'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:16:09

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Folder: Screening

Form: Risk of Exposure

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[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:24:55
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:10
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:24:51
User entered '0'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:16:09

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Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User entered '0'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:16:09



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Folder: Screening

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:24:55
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:10
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:24:51
User entered empty.	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:16:09

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:01:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:25:08
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:15
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:29:50
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:35:27

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:25:08
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:15
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:29:50
User entered '03 Aug 2020'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:35:27

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Folder: Visit 1 Day 1

Form: Visit Date

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:25:08
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:15
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:29:50
User entered 'Clinic (Clinic)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:35:27

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:01:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered 'VISIT1'	System	03 Aug 2020 15:35:27

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:27:01
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:19
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:32:10
User entered '03 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 15:19:33

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:01:20

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:27:01
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:19
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:32:10
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 01:43:21
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:43:21
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	03 Aug 2020 15:19:33
User entered '184450' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 15:19:33

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Form: Randomization

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[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:27:01
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:19
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:32:10
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 15:19:33



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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)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:27:01
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:19
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:32:10
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:35:56

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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)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:27:01
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:19
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:32:10
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:35:56

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Form: Randomization

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Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:27:01
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:19
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:32:10
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:35:56

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:01:20

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:27:01
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:19
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:32:10
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:35:56

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:01:20

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:27:01
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:19
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:32:10
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:35:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:01:20

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User closed query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:45:55
Query 'per query response, ND. Please enter "ND" directly into the database.' answered with 'Verified and updated' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 20:43:43
User entered missing code ND - Not Done; reason for change Per Query Resolution	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 20:43:22
User opened query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:46:57
User closed query 'Please enter ND into the data base.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:46:57
Query 'Please enter ND into the data base.' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	09 Nov 2020 16:22:36
User opened query 'Please enter ND into the data base.' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:55:21
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile ' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:55:21
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile ' answered with 'updated ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:19:39
DataPoint Un-verified.	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:19:29
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:19:29
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:42:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:10

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Height

Audit	User	Time (GMT)
User entered '67' in	Alyssa-Kay Peay (b) (4) (b) (4)	03 Aug 2020 16:15:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

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Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User closed query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:45:58
Query 'per query response, ND. Please enter "ND" directly into the database.' answered with 'Verified and updated' (Site from CRA).	Alyssa-Kay Peay (b) (4)	10 Nov 2020 20:43:54
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	10 Nov 2020 20:43:22
User opened query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:47:14
User closed query 'Please enter ND into the data base.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:47:14
Query 'Please enter ND into the data base.' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4)	09 Nov 2020 16:22:45
User opened query 'Please enter ND into the data base.' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:55:27
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:55:27
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:19:43
DataPoint Un-verified.	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:19:29
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:19:29
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:42:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:11



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Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:01:20

Weight

Audit	User	Time (GMT)
User entered '190' lb	Alyssa-Kay Peay (b) (4) (b) (4)	03 Aug 2020 16:15:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:01:20

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User closed query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:45:55
Query 'per query response, ND. Please enter "ND" directly into the database.' answered with 'Verified and updated' (Site from CRA).	Alyssa-Kay Peay (b) (4)	10 Nov 2020 20:43:43
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	10 Nov 2020 20:43:22
User opened query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:46:57
User closed query 'Please enter ND into the data base.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:46:57
Query 'Please enter ND into the data base.' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4)	09 Nov 2020 16:22:36
User opened query 'Please enter ND into the data base.' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:55:21
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:55:21
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' answered with 'updated ND' (Site from CRA).	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:19:39
DataPoint Un-verified.	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:19:29
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:19:29
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:42:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:10

US3832055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:01:20

Height

Audit	User	Time (GMT)
User entered '67' in	Alyssa-Kay Peay (b) (4) (b) (4)	03 Aug 2020 16:15:02

US3832055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:01:20

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User closed query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:45:58
Query 'per query response, ND. Please enter "ND" directly into the database.' answered with 'Verified and updated' (Site from CRA).	Alyssa-Kay Peay (b) (4)	10 Nov 2020 20:43:54
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	10 Nov 2020 20:43:22
User opened query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:47:14
User closed query 'Please enter ND into the data base.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:47:14
Query 'Please enter ND into the data base.' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4)	09 Nov 2020 16:22:45
User opened query 'Please enter ND into the data base.' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:55:27
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:55:27
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:19:43
DataPoint Un-verified.	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:19:29
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:19:29
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:42:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:11

US3832055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:01:20

Weight

Audit	User	Time (GMT)
User entered '190' lb	Alyssa-Kay Peay (b) (4) (b) (4)	03 Aug 2020 16:15:02

US3832055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:01:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User accepted default value 'Pre-Dose (PREDOSE)'	Alyssa-Kay Peay (b) (4) (b) (4)	03 Aug 2020 16:15:02

US3832055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:01:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:04
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 16:15:02

US3832055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:01:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:04
User entered '03 Aug 2020'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 16:15:02



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:01:20

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:04
User entered '10:41'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 16:15:02

US3832055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:01:20

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered '03 Aug 2020 10:41'	System	03 Aug 2020 16:15:02

US3832055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:01:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:04
User entered '98.2' F	Alyssa-Kay Peay (b) (4)	03 Aug 2020 16:15:02

US3832055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:01:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:04
User entered 'Oral (Oral)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 16:15:02

US3832055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:01:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:04
User entered empty.	Alyssa-Kay Peay (b) (4)	03 Aug 2020 16:15:02

US3832055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:01:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:04
User entered '78'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 16:15:02

US3832055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:01:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered 'bpm'	System	03 Aug 2020 16:15:02

US3832055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:01:20

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:04
User entered '16'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 16:15:02



US3832055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:01:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered 'breaths/min'	System	03 Aug 2020 16:15:02

US3832055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:01:20

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:04
User entered '146'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 16:15:02

US3832055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:01:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered 'mmHg'	System	03 Aug 2020 16:15:02

US3832055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:01:20

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:04
User entered '74'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 16:15:02

US3832055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:01:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered 'mmHg'	System	03 Aug 2020 16:15:02

US3832055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:01:20

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User closed query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:45:55
Query 'per query response, ND. Please enter "ND" directly into the database.' answered with 'Verified and updated' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 20:43:43
User entered missing code ND - Not Done; reason for change Per Query Resolution	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 20:43:22
User opened query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:46:57
User closed query 'Please enter ND into the data base.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:46:57
Query 'Please enter ND into the data base.' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	09 Nov 2020 16:22:36
User opened query 'Please enter ND into the data base.' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:55:21
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile ' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:55:21
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile ' answered with 'updated ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:19:39
DataPoint Un-verified.	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:19:29
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:19:29
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:42:50
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:10

US3832055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:01:20

Height

Audit	User	Time (GMT)
User entered '67' in	Alyssa-Kay Peay (b) (4) (b) (4)	03 Aug 2020 16:15:02

US3832055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:01:20

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User closed query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:45:58
Query 'per query response, ND. Please enter "ND" directly into the database.' answered with 'Verified and updated' (Site from CRA).	Alyssa-Kay Peay (b) (4)	10 Nov 2020 20:43:54
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	10 Nov 2020 20:43:22
User opened query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:47:14
User closed query 'Please enter ND into the data base.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:47:14
Query 'Please enter ND into the data base.' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4)	09 Nov 2020 16:22:45
User opened query 'Please enter ND into the data base.' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:55:27
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:55:27
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:19:43
DataPoint Un-verified.	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:19:29
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:19:29
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:42:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:11



US3832055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:01:20

Weight

Audit	User	Time (GMT)
User entered '190' lb	Alyssa-Kay Peay (b) (4) (b) (4)	03 Aug 2020 16:15:02

US3832055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:01:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User accepted default value 'Post-Dose (POSTDOSE)'	Alyssa-Kay Peay (b) (4) (b) (4)	03 Aug 2020 16:15:02

US3832055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:01:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:28
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 16:15:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:01:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:28
User entered '03 Aug 2020'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 16:15:02

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:01:20

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:28:28
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	18 Aug 2020 13:02:04
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		03 Aug 2020 16:15:02
User entered '12:02'	Alyssa-Kay Peay (b) (4) (b) (4)	03 Aug 2020 16:15:02

US3832055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:01:20

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered '03 Aug 2020 12:02'	System	03 Aug 2020 16:15:02

US3832055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:01:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:28
User entered '98.5' F	Alyssa-Kay Peay (b) (4)	03 Aug 2020 16:15:02

US3832055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:01:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:28
User entered 'Oral (Oral)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 16:15:02



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:01:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:28
User entered empty.	Alyssa-Kay Peay (b) (4)	03 Aug 2020 16:15:02

US3832055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:01:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:28
User entered '69'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 16:15:02

US3832055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:01:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered 'bpm'	System	03 Aug 2020 16:15:02

US3832055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:01:20

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:28
User entered '16'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 16:15:02

US3832055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:01:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered 'breaths/min'	System	03 Aug 2020 16:15:02

US3832055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:01:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:28
User entered '128'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 16:15:02

US3832055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:01:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered 'mmHg'	System	03 Aug 2020 16:15:02

US3832055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:01:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:28
User entered '79'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 16:15:02



US3832055

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:01:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered 'mmHg'	System	03 Aug 2020 16:15:02

US3832055

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:01:20

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User closed query 'Per EDC guidelines, NO must be recorded if Day 0 and Day 1 are performed on the same date, this is only entered on Day . Please verify and reconcile ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	08 Nov 2020 21:50:39
Query 'Per EDC guidelines, NO must be recorded if Day 0 and Day 1 are performed on the same date, this is only entered on Day . Please verify and reconcile ' answered with 'Updated per query ' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	05 Nov 2020 18:18:05
DataPoint Un-verified.	Danyel Johnson (b) (4) (b) (4)	05 Nov 2020 18:17:55
User entered 'No (N)' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	05 Nov 2020 18:17:55
User opened query 'Per EDC guidelines, NO must be recorded if Day 0 and Day 1 are performed on the same date, this is only entered on Day . Please verify and reconcile ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:42:01
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:21:13
Query 'Per source in CRIO, physical examination was not performed. Please verify and reconcile.' canceled (Site from CRA).	(b) (4), (b) (6)	30 Sep 2020 19:21:09
User opened query 'Per source in CRIO, physical examination was not performed. Please verify and reconcile.' (Site from CRA).	(b) (4), (b) (6)	29 Sep 2020 18:43:03
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	03 Aug 2020 15:36:06

US3832055

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:01:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User closed query 'Per EDC guidelines, NO must be recorded if Day 0 and Day 1 are performed on the same date, this is only entered on Day . Please verify and reconcile ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	08 Nov 2020 21:50:43
Query 'Per EDC guidelines, NO must be recorded if Day 0 and Day 1 are performed on the same date, this is only entered on Day . Please verify and reconcile ' answered with 'Updated per query ' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	05 Nov 2020 18:18:08
DataPoint Un-verified.	Danyel Johnson (b) (4) (b) (4)	05 Nov 2020 18:17:55
User entered empty; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	05 Nov 2020 18:17:55
User opened query 'Per EDC guidelines, NO must be recorded if Day 0 and Day 1 are performed on the same date, this is only entered on Day . Please verify and reconcile ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:42:07
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 19:21:13
User entered '03 Aug 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	03 Aug 2020 15:36:06

US3832055

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:01:20

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:53
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:23
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:43:20
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:36:39

US3832055

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:01:20

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:53
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:23
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:44:14
User entered empty.	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:36:39

US3832055

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:53
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:23
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:44:14
User entered empty.	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:36:39

US3832055

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:01:20

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered 'MRNA-1273 OR PLACEBO'	System	03 Aug 2020 15:36:39

US3832055

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:01:20

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:53
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:23
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:44:14
User entered '03 Aug 2020'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:36:39



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:01:20

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:53
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:23
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:44:14
User entered '11:32'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:36:39

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:01:20

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered '03 Aug 2020 11:32'	System	03 Aug 2020 15:36:39

US3832055

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:01:20

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:53
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:23
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:44:14
User entered 'Left Arm (LEFT ARM)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 15:36:39

US3832055

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:01:20

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:28:53
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:23
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:44:14
User entered 'ONCE'	System	03 Aug 2020 15:36:39

US3832055

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:01:20

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered 'INTRAMUSCULAR'	System	03 Aug 2020 15:36:39

US3832055

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:01:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:29:11
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:28
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:53:11
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 16:15:23

US3832055

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:01:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:29:11
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:28
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:53:11
User entered '03 Aug 2020'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 16:15:23

US3832055

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:01:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:29:11
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:28
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:53:11
User entered '11:16'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 16:15:23



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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:01:20

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered '03 Aug 2020 11:16'	System	03 Aug 2020 16:15:23

US3832055

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:01:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:29:33
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:32
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:53:39
User entered '03 Aug 2020'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 16:15:50

US3832055

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:01:20

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Alyssa-Kay Peay (b) (4) (b) (4)	03 Aug 2020 16:15:50

US3832055

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:01:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:29:33
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:32
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:53:39
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 16:15:50

US3832055

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:01:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:29:33
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:32
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:53:39
User entered '11:15'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 16:15:50

US3832055

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:01:20

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered '03 Aug 2020 11:15'	System	03 Aug 2020 16:15:50

US3832055

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:01:20

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 16:15:50

US3832055

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:01:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Un-verified.	(b) (4)	
	Alyssa-Kay Peay (b) (4)	10 Nov 2020 21:50:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 21:50:51
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:29:33
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:32
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:53:39
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 16:15:50
	(b) (4)	



US3832055

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:01:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Un-verified.	(b) (4)	
	Alyssa-Kay Peay (b) (4)	10 Nov 2020 21:50:51
User entered empty; reason for change Data Entry Error	(b) (4)	
	Alyssa-Kay Peay (b) (4)	10 Nov 2020 21:50:51
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:29:33
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:32
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:53:39
User entered '11:15'	(b) (4)	
	Alyssa-Kay Peay (b) (4)	03 Aug 2020 16:15:50
	(b) (4)	

US3832055

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:01:20

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered empty.	System	10 Nov 2020 21:50:51
User entered '03 Aug 2020 11:15'	System	03 Aug 2020 16:15:50

US3832055

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:01:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:29:39
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:36
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:53:46
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	03 Aug 2020 16:15:56

US3832055

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:01:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered 'I'	System	03 Aug 2020 16:15:56

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-03T12:03:24', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '730670c1-544a-40ae-a696-9d24aa9f18fe' User entered 'Yes (Y)'	System	03 Aug 2020 16:04:01
	System	03 Aug 2020 16:04:01

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-03T12:03:32', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '730670c1-544a-40ae-a696-9d24aa9f18fe' User entered '98.5'	System	03 Aug 2020 16:04:01
	System	03 Aug 2020 16:04:01

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-03T12:03:47', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '730670c1-544a-40ae-a696-9d24aa9f18fe' User entered 'No (N)'	System	03 Aug 2020 16:04:01
	System	03 Aug 2020 16:04:01



US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-03T12:03:59', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '730670c1-544a-40ae-a696-9d24aa9f18fe'	System	03 Aug 2020 16:04:01
User entered '03 Aug 2020 12:03'	System	03 Aug 2020 16:04:01

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '03 Aug 2020 11:52'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '03 Aug 2020 14:22'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-03T18:43:27', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '88d136d2-0bf3-4211-ac89-37b902bf617f' User entered 'Yes (Y)'	System	03 Aug 2020 22:43:52
	System	03 Aug 2020 22:43:52

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-03T18:43:36', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '88d136d2-0bf3-4211-ac89-37b902bf617f' User entered '93.6'	System	03 Aug 2020 22:43:52
	System	03 Aug 2020 22:43:52

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-03T18:43:41', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '88d136d2-0bf3-4211-ac89-37b902bf617f' User entered 'No (N)'	System	03 Aug 2020 22:43:52
	System	03 Aug 2020 22:43:52

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-03T18:43:47', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '88d136d2-0bf3-4211-ac89-37b902bf617f' User entered '03 Aug 2020 18:43'	System	03 Aug 2020 22:43:52
	System	03 Aug 2020 22:43:52



US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '03 Aug 2020 15:17'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered 'Day 2'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:01:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-04T20:47:10', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '9ce72f41-f449-455c-ab2e-a6512d15d011' User entered 'Yes (Y)'	System	05 Aug 2020 00:47:29
	System	05 Aug 2020 00:47:29

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:01:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-04T20:47:17', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '9ce72f41-f449-455c-ab2e-a6512d15d011' User entered '97.0'	System	05 Aug 2020 00:47:29
	System	05 Aug 2020 00:47:29

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-04T20:47:21', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '9ce72f41-f449-455c-ab2e-a6512d15d011'	System	05 Aug 2020 00:47:29
User entered 'No (N)'	System	05 Aug 2020 00:47:29

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-04T20:47:28', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '9ce72f41-f449-455c-ab2e-a6512d15d011' User entered '04 Aug 2020 20:47'	System	05 Aug 2020 00:47:29
	System	05 Aug 2020 00:47:29

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 15:36:39



US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered 'Day 3'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:01:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-05T19:02:48', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '094da30e-eac7-48d0-bb1c-35f0dc4f680c' User entered 'Yes (Y)'	System	05 Aug 2020 23:03:05
	System	05 Aug 2020 23:03:05

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:01:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-05T19:02:54', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '094da30e-eac7-48d0-bb1c-35f0dc4f680c' User entered '97.7'	System	05 Aug 2020 23:03:05
	System	05 Aug 2020 23:03:05

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-05T19:02:58', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '094da30e-eac7-48d0-bb1c-35f0dc4f680c'	System	05 Aug 2020 23:03:05
User entered 'No (N)'	System	05 Aug 2020 23:03:05

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-05T19:03:04', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '094da30e-eac7-48d0-bb1c-35f0dc4f680c'	System	05 Aug 2020 23:03:05
User entered '05 Aug 2020 19:03'	System	05 Aug 2020 23:03:05

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 15:36:39



US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered 'Day 4'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:01:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-06T19:29:58', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'a0fe5c70-d400-4e23-b895-c6167280ebeb' User entered 'Yes (Y)'	System	06 Aug 2020 23:30:15
	System	06 Aug 2020 23:30:15

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:01:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-06T19:30:06', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'a0fe5c70-d400-4e23-b895-c6167280ebeb' User entered '97.4'	System	06 Aug 2020 23:30:15
	System	06 Aug 2020 23:30:15

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-06T19:30:10', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'a0fe5c70-d400-4e23-b895-c6167280ebeb'	System	06 Aug 2020 23:30:15
User entered 'No (N)'	System	06 Aug 2020 23:30:15

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-06T19:30:13', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'a0fe5c70-d400-4e23-b895-c6167280ebeb' User entered '06 Aug 2020 19:30'	System	06 Aug 2020 23:30:15
	System	06 Aug 2020 23:30:15

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered 'Day 5'	System	03 Aug 2020 15:36:39



US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:01:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-08T05:59:37', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '463b0bb4-58b8-4754-9f81-e49efb44c249'	System	08 Aug 2020 10:00:03
User entered 'Yes (Y)'	System	08 Aug 2020 10:00:03

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:01:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-08T05:59:51', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '463b0bb4-58b8-4754-9f81-e49efb44c249' User entered '97.6'	System	08 Aug 2020 10:00:03
	System	08 Aug 2020 10:00:03

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-08T05:59:54', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '463b0bb4-58b8-4754-9f81-e49efb44c249'	System	08 Aug 2020 10:00:03
User entered 'No (N)'	System	08 Aug 2020 10:00:03

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-08T05:59:59', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '463b0bb4-58b8-4754-9f81-e49efb44c249'	System	08 Aug 2020 10:00:03
User entered '08 Aug 2020 05:59'	System	08 Aug 2020 10:00:03

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered 'Day 6'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:01:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-08T18:11:42', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'fa04e232-2f57-482a-8e78-c781e8fb1f0f'	System	08 Aug 2020 22:22:06
User entered 'Yes (Y)'	System	08 Aug 2020 22:22:06



US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:01:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-08T18:11:49', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'fa04e232-2f57-482a-8e78-c781e8fb1f0f' User entered '97.6'	System	08 Aug 2020 22:22:06
	System	08 Aug 2020 22:22:06

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-08T18:11:52', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'fa04e232-2f57-482a-8e78-c781e8fb1f0f'	System	08 Aug 2020 22:22:06
User entered 'No (N)'	System	08 Aug 2020 22:22:06

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-08T18:11:55', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'fa04e232-2f57-482a-8e78-c781e8fb1f0f'	System	08 Aug 2020 22:22:06
User entered '08 Aug 2020 18:11'	System	08 Aug 2020 22:22:06

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered 'Day 7'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:01:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-09T20:52:45', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'cd7c8f97-6166-4c9d-9a8e-b1b95bf2eb7f' User entered 'Yes (Y)'	System	10 Aug 2020 00:52:59
	System	10 Aug 2020 00:52:59

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:01:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-09T20:52:51', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'cd7c8f97-6166-4c9d-9a8e-b1b95bf2eb7f' User entered '98.1'	System	10 Aug 2020 00:52:59
	System	10 Aug 2020 00:52:59



US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-09T20:52:55', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'cd7c8f97-6166-4c9d-9a8e-b1b95bf2eb7f'	System	10 Aug 2020 00:52:59
User entered 'No (N)'	System	10 Aug 2020 00:52:59

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-09T20:52:58', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'cd7c8f97-6166-4c9d-9a8e-b1b95bf2eb7f' User entered '09 Aug 2020 20:52'	System	10 Aug 2020 00:52:59
	System	10 Aug 2020 00:52:59

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-03T12:04:15', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'f5d666cf-65af-4fb8-ad7a-e7a228fe4e23'	System	03 Aug 2020 16:04:52
User entered 'None (1)'	System	03 Aug 2020 16:04:52

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-03T12:04:27', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'f5d666cf-65af-4fb8-ad7a-e7a228fe4e23'	System	03 Aug 2020 16:04:52
User entered 'No (N)'	System	03 Aug 2020 16:04:52

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-03T12:04:29', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'f5d666cf-65af-4fb8-ad7a-e7a228fe4e23'	System	03 Aug 2020 16:04:52
User entered 'No (N)'	System	03 Aug 2020 16:04:52



US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-03T12:04:44', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'f5d666cf-65af-4fb8-ad7a-e7a228fe4e23'	System	03 Aug 2020 16:04:52
User entered 'None (1)'	System	03 Aug 2020 16:04:52

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-03T12:04:49', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'f5d666cf-65af-4fb8-ad7a-e7a228fe4e23'	System	03 Aug 2020 16:04:52
User entered '03 Aug 2020 12:04'	System	03 Aug 2020 16:04:52

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '03 Aug 2020 11:52'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '03 Aug 2020 14:22'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-03T18:43:54', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '83abc228-b05c-4883-b419-c993f84d89a5'	System	03 Aug 2020 22:44:25
User entered 'None (1)'	System	03 Aug 2020 22:44:25

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-03T18:43:57', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '83abc228-b05c-4883-b419-c993f84d89a5'	System	03 Aug 2020 22:44:25
User entered 'No (N)'	System	03 Aug 2020 22:44:25

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-03T18:44:00', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '83abc228-b05c-4883-b419-c993f84d89a5'	System	03 Aug 2020 22:44:25
User entered 'No (N)'	System	03 Aug 2020 22:44:25



US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-03T18:44:19', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '83abc228-b05c-4883-b419-c993f84d89a5'	System	03 Aug 2020 22:44:25
User entered 'None (1)'	System	03 Aug 2020 22:44:25

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-03T18:44:23', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '83abc228-b05c-4883-b419-c993f84d89a5'	System	03 Aug 2020 22:44:25
User entered '03 Aug 2020 18:44'	System	03 Aug 2020 22:44:25

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '03 Aug 2020 15:17'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered 'Day 2'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-04T20:47:40', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'e036e097-2951-4b5f-bef1-da1df9ee9fc7'	System	05 Aug 2020 00:48:14
User entered 'Does not interfere with activity (2)'	System	05 Aug 2020 00:48:14

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:01:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-04T20:47:44', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'e036e097-2951-4b5f-bef1-da1df9ee9fc7'	System	05 Aug 2020 00:48:14
User entered 'No (N)'	System	05 Aug 2020 00:48:14

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-04T20:47:48', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'e036e097-2951-4b5f-bef1-da1df9ee9fc7'	System	05 Aug 2020 00:48:14
User entered 'Yes (Y)'	System	05 Aug 2020 00:48:14



US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-04T20:47:59', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'e036e097-2951-4b5f-bef1-da1df9ee9fc7'	System	05 Aug 2020 00:48:14
User entered '6'	System	05 Aug 2020 00:48:14

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-04T20:48:03', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'e036e097-2951-4b5f-bef1-da1df9ee9fc7'	System	05 Aug 2020 00:48:14
User entered 'None (1)'	System	05 Aug 2020 00:48:14

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-04T20:48:12', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'e036e097-2951-4b5f-bef1-da1df9ee9fc7'	System	05 Aug 2020 00:48:14
User entered '04 Aug 2020 20:48'	System	05 Aug 2020 00:48:14

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered 'Day 3'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-05T19:03:10', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '19bea917-9ddc-4ed4-9643-824f04521375'	System	05 Aug 2020 23:03:40
User entered 'Does not interfere with activity (2)'	System	05 Aug 2020 23:03:40

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:01:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-05T19:03:14', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '19bea917-9ddc-4ed4-9643-824f04521375' User entered 'No (N)'	System	05 Aug 2020 23:03:40
	System	05 Aug 2020 23:03:40



US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-05T19:03:19', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '19bea917-9ddc-4ed4-9643-824f04521375' User entered 'Yes (Y)'	System	05 Aug 2020 23:03:40
	System	05 Aug 2020 23:03:40

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-05T19:03:25', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '19bea917-9ddc-4ed4-9643-824f04521375' User entered '6'	System	05 Aug 2020 23:03:40
	System	05 Aug 2020 23:03:40

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-05T19:03:31', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '19bea917-9ddc-4ed4-9643-824f04521375'	System	05 Aug 2020 23:03:40
User entered 'None (1)'	System	05 Aug 2020 23:03:40

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-05T19:03:35', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '19bea917-9ddc-4ed4-9643-824f04521375' User entered '05 Aug 2020 19:03'	System	05 Aug 2020 23:03:40
	System	05 Aug 2020 23:03:40

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered 'Day 4'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-06T19:30:20', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '32ec7ddb-bc56-4910-b99b-c21399988d2f' User entered 'None (1)'	System	06 Aug 2020 23:30:48
	System	06 Aug 2020 23:30:48



US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:01:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-06T19:30:23', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '32ec7ddb-bc56-4910-b99b-c21399988d2f' User entered 'No (N)'	System	06 Aug 2020 23:30:48
	System	06 Aug 2020 23:30:48

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-06T19:30:27', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '32ec7ddb-bc56-4910-b99b-c21399988d2f' User entered 'No (N)'	System	06 Aug 2020 23:30:48
	System	06 Aug 2020 23:30:48

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-06T19:30:41', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '32ec7ddb-bc56-4910-b99b-c21399988d2f' User entered 'None (1)'	System	06 Aug 2020 23:30:48
	System	06 Aug 2020 23:30:48

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-06T19:30:46', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '32ec7ddb-bc56-4910-b99b-c21399988d2f' User entered '06 Aug 2020 19:30'	System	06 Aug 2020 23:30:48
	System	06 Aug 2020 23:30:48

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered 'Day 5'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-08T06:00:14', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '65c1bb82-267b-4f5d-b357-16bb1d17112f'	System	08 Aug 2020 10:00:33
User entered 'Does not interfere with activity (2)'	System	08 Aug 2020 10:00:33



US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:01:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-08T06:00:17', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '65c1bb82-267b-4f5d-b357-16bb1d17112f' User entered 'No (N)'	System	08 Aug 2020 10:00:33
	System	08 Aug 2020 10:00:33

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-08T06:00:21', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '65c1bb82-267b-4f5d-b357-16bb1d17112f' User entered 'No (N)'	System	08 Aug 2020 10:00:33
	System	08 Aug 2020 10:00:33

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-08T06:00:24', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '65c1bb82-267b-4f5d-b357-16bb1d17112f' User entered 'None (1)'	System	08 Aug 2020 10:00:33
	System	08 Aug 2020 10:00:33

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-08T06:00:30', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '65c1bb82-267b-4f5d-b357-16bb1d17112f' User entered '08 Aug 2020 06:00'	System	08 Aug 2020 10:00:33
	System	08 Aug 2020 10:00:33

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered 'Day 6'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-08T18:12:05', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'a3729a0f-1908-43d7-914b-469d85fb4bf6'	System	08 Aug 2020 22:12:29
User entered 'None (1)'	System	08 Aug 2020 22:12:29



US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:01:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-08T18:12:09', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'a3729a0f-1908-43d7-914b-469d85fb4bf6'	System	08 Aug 2020 22:12:29
User entered 'No (N)'	System	08 Aug 2020 22:12:29

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-08T18:12:12', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'a3729a0f-1908-43d7-914b-469d85fb4bf6'	System	08 Aug 2020 22:12:29
User entered 'No (N)'	System	08 Aug 2020 22:12:29

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-08T18:12:22', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'a3729a0f-1908-43d7-914b-469d85fb4bf6'	System	08 Aug 2020 22:12:29
User entered 'None (1)'	System	08 Aug 2020 22:12:29

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-08T18:12:25', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'a3729a0f-1908-43d7-914b-469d85fb4bf6'	System	08 Aug 2020 22:12:29
User entered '08 Aug 2020 18:12'	System	08 Aug 2020 22:12:29

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered 'Day 7'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-09T20:53:03', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'cb1078ce-aaa8-4ccf-ba09-a3b22b4d6cd7'	System	10 Aug 2020 00:53:22
User entered 'None (1)'	System	10 Aug 2020 00:53:22



US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:01:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-09T20:53:05', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'cb1078ce-aaa8-4ccf-ba09-a3b22b4d6cd7'	System	10 Aug 2020 00:53:22
User entered 'No (N)'	System	10 Aug 2020 00:53:22

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-09T20:53:09', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'cb1078ce-aaa8-4ccf-ba09-a3b22b4d6cd7'	System	10 Aug 2020 00:53:22
User entered 'No (N)'	System	10 Aug 2020 00:53:22

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-09T20:53:18', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'cb1078ce-aaa8-4ccf-ba09-a3b22b4d6cd7'	System	10 Aug 2020 00:53:22
User entered 'None (1)'	System	10 Aug 2020 00:53:22

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-09T20:53:21', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'cb1078ce-aaa8-4ccf-ba09-a3b22b4d6cd7'	System	10 Aug 2020 00:53:22
User entered '09 Aug 2020 20:53'	System	10 Aug 2020 00:53:22

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-03T12:05:15', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '481f4b09-cdac-4baa-b1cf-fac7831fd86e' User entered 'None (0)'	System	03 Aug 2020 16:05:47
	System	03 Aug 2020 16:05:47



US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-03T12:05:26', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '481f4b09-cdac-4baa-b1cf-fac7831fd86e' User entered 'None (0)'	System	03 Aug 2020 16:05:47
	System	03 Aug 2020 16:05:47

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-03T12:05:29', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '481f4b09-cdac-4baa-b1cf-fac7831fd86e' User entered 'None (0)'	System	03 Aug 2020 16:05:47
	System	03 Aug 2020 16:05:47

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-03T12:05:32', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '481f4b09-cdac-4baa-b1cf-fac7831fd86e' User entered 'None (0)'	System	03 Aug 2020 16:05:47
	System	03 Aug 2020 16:05:47

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-03T12:05:35', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '481f4b09-cdac-4baa-b1cf-fac7831fd86e' User entered 'None (0)'	System	03 Aug 2020 16:05:47
	System	03 Aug 2020 16:05:47

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-03T12:05:38', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '481f4b09-cdac-4baa-b1cf-fac7831fd86e' User entered 'None (0)'	System	03 Aug 2020 16:05:47
	System	03 Aug 2020 16:05:47

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-03T12:05:42', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '481f4b09-cdac-4baa-b1cf-fac7831fd86e'	System	03 Aug 2020 16:05:47
User entered 'No (N)'	System	03 Aug 2020 16:05:47

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-03T12:05:45', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '481f4b09-cdac-4baa-b1cf-fac7831fd86e'	System	03 Aug 2020 16:05:47
User entered '03 Aug 2020 12:05'	System	03 Aug 2020 16:05:47

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '03 Aug 2020 11:52'	System	03 Aug 2020 15:36:39



US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '03 Aug 2020 14:22'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-03T18:44:28', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '7201cb15-832d-4b8f-a697-8d9d9d74e5f2'	System	03 Aug 2020 22:44:55
User entered 'None (0)'	System	03 Aug 2020 22:44:55

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-03T18:44:33', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '7201cb15-832d-4b8f-a697-8d9d9d74e5f2'	System	03 Aug 2020 22:44:55
User entered 'None (0)'	System	03 Aug 2020 22:44:55

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-03T18:44:36', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '7201cb15-832d-4b8f-a697-8d9d9d74e5f2'	System	03 Aug 2020 22:44:55
User entered 'None (0)'	System	03 Aug 2020 22:44:55

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-03T18:44:39', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '7201cb15-832d-4b8f-a697-8d9d9d74e5f2'	System	03 Aug 2020 22:44:55
User entered 'None (0)'	System	03 Aug 2020 22:44:55

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-03T18:44:42', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '7201cb15-832d-4b8f-a697-8d9d9d74e5f2'	System	03 Aug 2020 22:44:55
User entered 'None (0)'	System	03 Aug 2020 22:44:55

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-03T18:44:45', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '7201cb15-832d-4b8f-a697-8d9d9d74e5f2'	System	03 Aug 2020 22:44:55
User entered 'None (0)'	System	03 Aug 2020 22:44:55



US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-03T18:44:51', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '7201cb15-832d-4b8f-a697-8d9d9d74e5f2'	System	03 Aug 2020 22:44:55
User entered 'No (N)'	System	03 Aug 2020 22:44:55

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-03T18:44:53', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '7201cb15-832d-4b8f-a697-8d9d9d74e5f2'	System	03 Aug 2020 22:44:55
User entered '03 Aug 2020 18:44'	System	03 Aug 2020 22:44:55

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '03 Aug 2020 15:17'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered 'Day 2'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:01:20

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-04T20:48:41', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '2b227b7a-e5ea-47fd-8abf-5f1337219e6f' User entered 'No interference with activity (1)'	System	05 Aug 2020 00:49:13
	System	05 Aug 2020 00:49:13

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:01:20

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-04T20:48:38', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '2b227b7a-e5ea-47fd-8abf-5f1337219e6f' User entered 'None (0)'	System	05 Aug 2020 00:49:13
	System	05 Aug 2020 00:49:13

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:01:20

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-04T20:48:46', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '2b227b7a-e5ea-47fd-8abf-5f1337219e6f' User entered 'None (0)'	System	05 Aug 2020 00:49:13
	System	05 Aug 2020 00:49:13



US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:01:20

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-04T20:48:49', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '2b227b7a-e5ea-47fd-8abf-5f1337219e6f' User entered 'None (0)'	System	05 Aug 2020 00:49:13
	System	05 Aug 2020 00:49:13

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:01:20

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-04T20:48:54', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '2b227b7a-e5ea-47fd-8abf-5f1337219e6f' User entered 'None (0)'	System	05 Aug 2020 00:49:13
	System	05 Aug 2020 00:49:13

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:01:20

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-04T20:48:57', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '2b227b7a-e5ea-47fd-8abf-5f1337219e6f' User entered 'None (0)'	System	05 Aug 2020 00:49:13
	System	05 Aug 2020 00:49:13

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-04T20:49:01', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '2b227b7a-e5ea-47fd-8abf-5f1337219e6f' User entered 'No (N)'	System	05 Aug 2020 00:49:13
	System	05 Aug 2020 00:49:13

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:01:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-04T20:49:09', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '2b227b7a-e5ea-47fd-8abf-5f1337219e6f' User entered '04 Aug 2020 20:49'	System	05 Aug 2020 00:49:13
	System	05 Aug 2020 00:49:13

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered 'Day 3'	System	03 Aug 2020 15:36:39



US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:01:20

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-05T19:03:41', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '77428c80-9a54-4935-b71c-e708733db2b2'	System	05 Aug 2020 23:04:05
User entered 'None (0)'	System	05 Aug 2020 23:04:05

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:01:20

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-05T19:03:45', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '77428c80-9a54-4935-b71c-e708733db2b2'	System	05 Aug 2020 23:04:05
User entered 'None (0)'	System	05 Aug 2020 23:04:05

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:01:20

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-05T19:03:48', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '77428c80-9a54-4935-b71c-e708733db2b2'	System	05 Aug 2020 23:04:05
User entered 'None (0)'	System	05 Aug 2020 23:04:05

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:01:20

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-05T19:03:51', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '77428c80-9a54-4935-b71c-e708733db2b2'	System	05 Aug 2020 23:04:05
User entered 'None (0)'	System	05 Aug 2020 23:04:05

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:01:20

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-05T19:03:53', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '77428c80-9a54-4935-b71c-e708733db2b2'	System	05 Aug 2020 23:04:05
User entered 'None (0)'	System	05 Aug 2020 23:04:05

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:01:20

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-05T19:03:57', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '77428c80-9a54-4935-b71c-e708733db2b2'	System	05 Aug 2020 23:04:05
User entered 'None (0)'	System	05 Aug 2020 23:04:05

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-05T19:04:00', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '77428c80-9a54-4935-b71c-e708733db2b2'	System	05 Aug 2020 23:04:05
User entered 'No (N)'	System	05 Aug 2020 23:04:05

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:01:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-05T19:04:03', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '77428c80-9a54-4935-b71c-e708733db2b2'	System	05 Aug 2020 23:04:05
User entered '05 Aug 2020 19:04'	System	05 Aug 2020 23:04:05



US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered 'Day 4'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:01:20

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-06T19:30:51', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '30fe8030-5ef9-4786-9d55-9454d00c7d7d' User entered 'None (0)'	System	06 Aug 2020 23:31:19
	System	06 Aug 2020 23:31:19

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:01:20

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-06T19:30:56', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '30fe8030-5ef9-4786-9d55-9454d00c7d7d' User entered 'None (0)'	System	06 Aug 2020 23:31:19
	System	06 Aug 2020 23:31:19

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:01:20

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-06T19:31:00', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '30fe8030-5ef9-4786-9d55-9454d00c7d7d' User entered 'None (0)'	System	06 Aug 2020 23:31:19
	System	06 Aug 2020 23:31:19

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:01:20

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-06T19:31:04', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '30fe8030-5ef9-4786-9d55-9454d00c7d7d' User entered 'None (0)'	System	06 Aug 2020 23:31:19
	System	06 Aug 2020 23:31:19

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:01:20

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-06T19:31:07', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '30fe8030-5ef9-4786-9d55-9454d00c7d7d' User entered 'None (0)'	System	06 Aug 2020 23:31:19
	System	06 Aug 2020 23:31:19



US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:01:20

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-06T19:31:10', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '30fe8030-5ef9-4786-9d55-9454d00c7d7d' User entered 'None (0)'	System	06 Aug 2020 23:31:19
	System	06 Aug 2020 23:31:19

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-06T19:31:13', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '30fe8030-5ef9-4786-9d55-9454d00c7d7d' User entered 'No (N)'	System	06 Aug 2020 23:31:19
	System	06 Aug 2020 23:31:19

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:01:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-06T19:31:15', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '30fe8030-5ef9-4786-9d55-9454d00c7d7d'	System	06 Aug 2020 23:31:19
User entered '06 Aug 2020 19:31'	System	06 Aug 2020 23:31:19

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered 'Day 5'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:01:20

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-08T06:00:36', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'd0112d1e-71ee-4403-863a-17d693f3da12'	System	08 Aug 2020 10:01:07
User entered 'None (0)'	System	08 Aug 2020 10:01:07

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:01:20

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-08T06:00:41', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'd0112d1e-71ee-4403-863a-17d693f3da12'	System	08 Aug 2020 10:01:07
User entered 'None (0)'	System	08 Aug 2020 10:01:07



US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:01:20

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-08T06:00:44', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'd0112d1e-71ee-4403-863a-17d693f3da12' User entered 'None (0)'	System	08 Aug 2020 10:01:07
	System	08 Aug 2020 10:01:07

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:01:20

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-08T06:00:46', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'd0112d1e-71ee-4403-863a-17d693f3da12' User entered 'None (0)'	System	08 Aug 2020 10:01:07
	System	08 Aug 2020 10:01:07

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:01:20

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-08T06:00:50', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'd0112d1e-71ee-4403-863a-17d693f3da12' User entered 'None (0)'	System	08 Aug 2020 10:01:07
	System	08 Aug 2020 10:01:07

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:01:20

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-08T06:00:57', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'd0112d1e-71ee-4403-863a-17d693f3da12' User entered 'None (0)'	System	08 Aug 2020 10:01:07
	System	08 Aug 2020 10:01:07

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-08T06:01:01', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'd0112d1e-71ee-4403-863a-17d693f3da12'	System	08 Aug 2020 10:01:07
User entered 'No (N)'	System	08 Aug 2020 10:01:07

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:01:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-08T06:01:04', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'd0112d1e-71ee-4403-863a-17d693f3da12'	System	08 Aug 2020 10:01:07
User entered '08 Aug 2020 06:01'	System	08 Aug 2020 10:01:07

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 15:36:39



US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered 'Day 6'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:01:20

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-08T18:12:31', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '9f24cdff-1f9a-474e-ae5e-b32bf11710c0'	System	08 Aug 2020 22:13:01
User entered 'None (0)'	System	08 Aug 2020 22:13:01

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:01:20

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-08T18:12:34', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '9f24cdff-1f9a-474e-ae5e-b32bf11710c0' User entered 'None (0)'	System	08 Aug 2020 22:13:01
	System	08 Aug 2020 22:13:01

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:01:20

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-08T18:12:37', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '9f24cdff-1f9a-474e-ae5e-b32bf11710c0' User entered 'None (0)'	System	08 Aug 2020 22:13:01
	System	08 Aug 2020 22:13:01

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:01:20

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-08T18:12:39', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '9f24cdff-1f9a-474e-ae5e-b32bf11710c0' User entered 'None (0)'	System	08 Aug 2020 22:13:01
	System	08 Aug 2020 22:13:01

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:01:20

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-08T18:12:42', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '9f24cdf-1f9a-474e-ae5e-b32bf11710c0' User entered 'None (0)'	System	08 Aug 2020 22:13:01
	System	08 Aug 2020 22:13:01

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:01:20

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-08T18:12:44', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '9f24cdff-1f9a-474e-ae5e-b32bf11710c0'	System	08 Aug 2020 22:13:01
User entered 'None (0)'	System	08 Aug 2020 22:13:01

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-08T18:12:48', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '9f24cdff-1f9a-474e-ae5e-b32bf11710c0'	System	08 Aug 2020 22:13:01
User entered 'No (N)'	System	08 Aug 2020 22:13:01



US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:01:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-08T18:12:51', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '9f24cdff-1f9a-474e-ae5e-b32bf11710c0'	System	08 Aug 2020 22:13:01
User entered '08 Aug 2020 18:12'	System	08 Aug 2020 22:13:01

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered 'Day 7'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:01:20

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-09T20:53:26', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '97bc7535-3837-46d1-8f3f-048917aae0ac'	System	10 Aug 2020 00:53:49
User entered 'None (0)'	System	10 Aug 2020 00:53:49

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:01:20

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-09T20:53:29', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '97bc7535-3837-46d1-8f3f-048917aae0ac' User entered 'None (0)'	System	10 Aug 2020 00:53:49
	System	10 Aug 2020 00:53:49

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:01:20

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-09T20:53:32', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '97bc7535-3837-46d1-8f3f-048917aae0ac' User entered 'None (0)'	System	10 Aug 2020 00:53:49
	System	10 Aug 2020 00:53:49

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:01:20

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-09T20:53:35', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '97bc7535-3837-46d1-8f3f-048917aae0ac'	System	10 Aug 2020 00:53:49
User entered 'None (0)'	System	10 Aug 2020 00:53:49



US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:01:20

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-09T20:53:38', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '97bc7535-3837-46d1-8f3f-048917aae0ac'	System	10 Aug 2020 00:53:49
User entered 'None (0)'	System	10 Aug 2020 00:53:49

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:01:20

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-09T20:53:40', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '97bc7535-3837-46d1-8f3f-048917aae0ac' User entered 'None (0)'	System	10 Aug 2020 00:53:49
	System	10 Aug 2020 00:53:49

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-09T20:53:44', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '97bc7535-3837-46d1-8f3f-048917aae0ac'	System	10 Aug 2020 00:53:49
User entered 'No (N)'	System	10 Aug 2020 00:53:49

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:01:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-08-09T20:53:47', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '97bc7535-3837-46d1-8f3f-048917aae0ac'	System	10 Aug 2020 00:53:49
User entered '09 Aug 2020 20:53'	System	10 Aug 2020 00:53:49

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 15:36:39

US3832055

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 15:36:39

US3832055

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:36:20
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:42
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:57:10
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 18:50:25

US3832055

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:36:20
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:42
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:57:10
User entered '10 Aug 2020'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 18:50:25



US3832055

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:36:20
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:42
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:57:10
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 18:50:25

US3832055

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:36:20
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:42
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:57:10
User entered empty.	Alyssa-Kay Peay (b) (4)	10 Aug 2020 18:50:25

US3832055

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:01:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:37:00
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:47
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:57:16
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	10 Aug 2020 18:50:31

US3832055

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:01:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered 'I'	System	10 Aug 2020 18:50:31

US3832055

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:37:23
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:52
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:57:39
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	17 Aug 2020 16:22:14

US3832055

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:37:23
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:52
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:57:39
User entered '17 Aug 2020'	Alyssa-Kay Peay (b) (4)	17 Aug 2020 16:22:14

US3832055

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:37:23
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:52
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:57:39
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Ashten Sheriff (b) (4)	17 Aug 2020 21:15:40
User entered 'Contact Not Made (CONTACT NOT MADE)'	Alyssa-Kay Peay (b) (4)	17 Aug 2020 16:22:14

US3832055

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:37:23
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:06:52
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:57:39
User entered 'LVM - contact made at 1715' reason for change: Data Entry Error	Ashten Sheriff (b) (4)	17 Aug 2020 21:15:40
User entered 'LVM'	Alyssa-Kay Peay (b) (4)	17 Aug 2020 16:22:14



US3832055

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:01:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 02:06:58
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:57:47
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Aug 2020 16:22:23

US3832055

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:01:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:54
User entered 'I'	System	17 Aug 2020 16:22:23

US3832055

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 02:07:02
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:58:18
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	24 Aug 2020 19:49:08

US3832055

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:07:02
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:58:18
User entered '24 Aug 2020'	Alyssa-Kay Peay (b) (4)	24 Aug 2020 19:49:08

US3832055

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 02:07:02
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:58:18
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4) (b) (4)	24 Aug 2020 19:49:08

US3832055

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 02:07:02
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:58:18
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	24 Aug 2020 19:49:08

US3832055

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:01:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 02:07:06
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:58:28
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	24 Aug 2020 19:49:01

US3832055

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:01:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:14:54
User entered 'I'	System	24 Aug 2020 19:49:01



US3832055

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:01:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:07:11
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:58:54
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	09 Sep 2020 13:22:25

US3832055

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:01:20

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 02:07:11
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:58:54
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	24 Sep 2020 09:54:30
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'Visit was conducted out of window secondary to receiving the Flu vaccine 8/25/2020' (Site from System).	Alyssa-Kay Peay (b) (4) (b) (4)	21 Sep 2020 17:03:49
Amendment Manager: User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	16 Sep 2020 23:41:02
Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 15:02:13
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	09 Sep 2020 13:22:25
User entered '9 Sep 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	09 Sep 2020 13:22:25

US3832055

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:07:11
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:58:54
User entered 'Clinic (Clinic)'	Alyssa-Kay Peay (b) (4)	09 Sep 2020 13:22:25

US3832055

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:01:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered 'VISIT2'	System	09 Sep 2020 13:22:25

US3832055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:01:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User accepted default value 'Pre-Dose (PREDOSE)'	Emma Partin (b) (4) (b) (4)	09 Sep 2020 21:43:18

US3832055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:01:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:21
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:07:15
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:59:59
User entered 'Yes (Y)'	Emma Partin (b) (4)	09 Sep 2020 21:43:18

US3832055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:01:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:21
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:07:15
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:59:59
User entered '09 Sep 2020'	Emma Partin (b) (4)	09 Sep 2020 21:43:18

US3832055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:01:20

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:21
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:07:15
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:59:59
User entered '08:55'	Emma Partin (b) (4)	09 Sep 2020 21:43:18



US3832055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:01:20

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered '09 Sep 2020 08:55'	System	09 Sep 2020 21:43:18

US3832055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:01:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:21
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:07:15
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:59:59
User entered '98.3' F	Emma Partin (b) (4)	09 Sep 2020 21:43:18

US3832055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:01:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 02:07:15
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:59:59
User entered 'Oral (Oral)'	Emma Partin (b) (4) (b) (4)	09 Sep 2020 21:43:18

US3832055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:01:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:21
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:07:15
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:59:59
User entered empty.	Emma Partin (b) (4)	09 Sep 2020 21:43:18

US3832055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:01:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 02:07:15
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:59:59
User entered '65'	Emma Partin (b) (4) (b) (4)	09 Sep 2020 21:43:18

US3832055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:01:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered 'bpm'	System	09 Sep 2020 21:43:18

US3832055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:01:20

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:21
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:07:15
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:59:59
User entered '14'	Emma Partin (b) (4)	09 Sep 2020 21:43:18

US3832055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:01:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered 'breaths/min'	System	09 Sep 2020 21:43:18



US3832055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:01:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:21
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:07:15
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:59:59
User entered '148'	Emma Partin (b) (4)	09 Sep 2020 21:43:18

US3832055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:01:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered 'mmHg'	System	09 Sep 2020 21:43:18

US3832055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:01:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:21
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:07:15
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:59:59
User entered '77'	Emma Partin (b) (4)	09 Sep 2020 21:43:18

US3832055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:01:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered 'mmHg'	System	09 Sep 2020 21:43:18

US3832055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:01:20

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User accepted default value 'Post-Dose (POSTDOSE)'	Emma Partin (b) (4) (b) (4)	09 Sep 2020 21:43:18

US3832055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:01:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:21
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 02:07:15
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:59:59
User entered 'Yes (Y)'	Emma Partin (b) (4) (b) (4)	09 Sep 2020 21:43:18

US3832055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:01:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:21
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:07:15
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:59:59
User entered '09 Sep 2020'	Emma Partin (b) (4)	09 Sep 2020 21:43:18

US3832055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:01:20

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:21
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:07:15
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:59:59
User entered '09:47'	Emma Partin (b) (4)	09 Sep 2020 21:43:18



US3832055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:01:20

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered '09 Sep 2020 09:47'	System	09 Sep 2020 21:43:18

US3832055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:01:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:21
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:07:15
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:59:59
User entered '98.4' F	Emma Partin (b) (4)	09 Sep 2020 21:43:18

US3832055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:01:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:21
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:07:15
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:59:59
User entered 'Oral (Oral)'	Emma Partin (b) (4)	09 Sep 2020 21:43:18

US3832055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:01:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:21
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:07:15
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:59:59
User entered empty.	Emma Partin (b) (4)	09 Sep 2020 21:43:18

US3832055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:01:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:21
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:07:15
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:59:59
User entered '61'	Emma Partin (b) (4)	09 Sep 2020 21:43:18

US3832055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:01:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered 'bpm'	System	09 Sep 2020 21:43:18

US3832055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:01:20

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:21
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:07:15
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:59:59
User entered '14'	Emma Partin (b) (4)	09 Sep 2020 21:43:18

US3832055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:01:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered 'breaths/min'	System	09 Sep 2020 21:43:18



US3832055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:01:20

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:21
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:07:15
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:59:59
User entered '146'	Emma Partin (b) (4)	09 Sep 2020 21:43:18

US3832055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:01:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered 'mmHg'	System	09 Sep 2020 21:43:18

US3832055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:01:20

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:21
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:07:15
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 18:59:59
User entered '79'	Emma Partin (b) (4)	09 Sep 2020 21:43:18

US3832055

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:01:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered 'mmHg'	System	09 Sep 2020 21:43:18

US3832055

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:01:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 02:07:20
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:01:27
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	09 Sep 2020 13:22:37

US3832055

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:01:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:07:20
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:01:27
User entered '9 Sep 2020'	Alyssa-Kay Peay (b) (4)	09 Sep 2020 13:22:37

US3832055

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:01:20

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 02:07:24
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:02:02
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	09 Sep 2020 13:22:53

US3832055

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:01:20

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:07:24
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:02:02
User entered empty.	Alyssa-Kay Peay (b) (4)	09 Sep 2020 13:22:53



US3832055

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:07:24
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:02:02
User entered empty.	Alyssa-Kay Peay (b) (4)	09 Sep 2020 13:22:53

US3832055

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:01:20

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered 'MRNA-1273 OR PLACEBO'	System	09 Sep 2020 13:22:53

US3832055

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:01:20

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:07:24
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:02:02
User entered '9 Sep 2020'	Alyssa-Kay Peay (b) (4)	09 Sep 2020 13:22:53

US3832055

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:01:20

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:07:24
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:02:02
User entered '09:17'	Alyssa-Kay Peay (b) (4)	09 Sep 2020 13:22:53

US3832055

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:01:20

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered '9 Sep 2020 09:17'	System	09 Sep 2020 13:22:53

US3832055

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:01:20

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:07:24
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:02:02
User entered 'Left Arm (LEFT ARM)'	Alyssa-Kay Peay (b) (4)	09 Sep 2020 13:22:53

US3832055

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:01:20

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:07:24
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:02:02
User entered 'ONCE'	System	09 Sep 2020 13:22:53

US3832055

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:01:20

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered 'INTRAMUSCULAR'	System	09 Sep 2020 13:22:53



US3832055

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:01:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 02:07:29
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:02:22
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	09 Sep 2020 13:23:03

US3832055

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:01:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:07:29
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:02:22
User entered '9 Sep 2020'	Alyssa-Kay Peay (b) (4)	09 Sep 2020 13:23:03

US3832055

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:01:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:07:29
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:02:22
User entered '09:11'	Alyssa-Kay Peay (b) (4)	09 Sep 2020 13:23:03

US3832055

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:01:20

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered '9 Sep 2020 09:11'	System	09 Sep 2020 13:23:03

US3832055

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:01:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:07:32
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:02:36
User entered '9 Sep 2020'	Alyssa-Kay Peay (b) (4)	09 Sep 2020 13:23:36

US3832055

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:01:20

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Alyssa-Kay Peay (b) (4) (b) (4)	09 Sep 2020 13:23:36

US3832055

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:01:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 02:07:32
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:02:36
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	09 Sep 2020 13:23:36

US3832055

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:01:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:07:32
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:02:36
User entered '09:07'	Alyssa-Kay Peay (b) (4)	09 Sep 2020 13:23:36



US3832055

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:01:20

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered '9 Sep 2020 09:07'	System	09 Sep 2020 13:23:36

US3832055

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:01:20

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Alyssa-Kay Peay (b) (4)	09 Sep 2020 13:23:36

US3832055

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:01:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 21:51:11
DataPoint Un-verified.	Alyssa-Kay Peay (b) (4)	01 Oct 2020 02:07:32
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:02:36
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	09 Sep 2020 13:23:36

US3832055

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:01:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User entered empty; reason for change Data Entry Error	(b) (4)	
DataPoint Un-verified.	Alyssa-Kay Peay (b) (4)	10 Nov 2020 21:51:11
DataPoint Verified.	(b) (4)	
User entered '09:07'	(b) (4), (b) (6)	01 Oct 2020 02:07:32
	(b) (4), (b) (6)	29 Sep 2020 19:02:36
	Alyssa-Kay Peay (b) (4)	09 Sep 2020 13:23:36
	(b) (4)	

US3832055

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:01:20

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered empty.	System	10 Nov 2020 21:51:11
User entered '9 Sep 2020 09:07'	System	09 Sep 2020 13:23:36

US3832055

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:01:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:07:37
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:02:45
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	09 Sep 2020 13:23:42

US3832055

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:01:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered 'I'	System	09 Sep 2020 13:23:42

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	09 Sep 2020 13:22:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 13:22:53



US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-09T09:48:32', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '9f158ec4-c335-4043-bd26-728b6a459eb6' User entered 'Yes (Y)'	System	09 Sep 2020 13:48:55
	System	09 Sep 2020 13:48:55

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-09T09:48:42', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '9f158ec4-c335-4043-bd26-728b6a459eb6' User entered '98.4'	System	09 Sep 2020 13:48:55
	System	09 Sep 2020 13:48:55

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-09T09:48:45', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '9f158ec4-c335-4043-bd26-728b6a459eb6' User entered 'No (N)'	System	09 Sep 2020 13:48:55
	System	09 Sep 2020 13:48:55

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-09T09:48:52', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '9f158ec4-c335-4043-bd26-728b6a459eb6' User entered '09 Sep 2020 09:48'	System	09 Sep 2020 13:48:55
	System	09 Sep 2020 13:48:55

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '09 Sep 2020 09:37'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '09 Sep 2020 12:07'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	09 Sep 2020 13:22:53
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-09T20:51:42', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '0aef7e05-a162-4d71-97db-b8ec5f25c3c4' User entered 'Yes (Y)'	System	10 Sep 2020 00:52:04
	System	10 Sep 2020 00:52:04



US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-09T20:51:50', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '0aef7e05-a162-4d71-97db-b8ec5f25c3c4' User entered '97.1'	System	10 Sep 2020 00:52:04
	System	10 Sep 2020 00:52:04

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-09T20:51:54', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '0aef7e05-a162-4d71-97db-b8ec5f25c3c4'	System	10 Sep 2020 00:52:04
User entered 'No (N)'	System	10 Sep 2020 00:52:04

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-09T20:51:58', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '0aef7e05-a162-4d71-97db-b8ec5f25c3c4' User entered '09 Sep 2020 20:51'	System	10 Sep 2020 00:52:04
	System	10 Sep 2020 00:52:04

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '09 Sep 2020 13:02'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	09 Sep 2020 13:22:53
User entered 'Day 2'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:01:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-10T19:47:48', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'e3fdb81-09f8-44ab-9dca-85d408608ba2'	System	10 Sep 2020 23:48:10
User entered 'Yes (Y)'	System	10 Sep 2020 23:48:10

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:01:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-10T19:47:55', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'e3fdb81-09f8-44ab-9dca-85d408608ba2' User entered '97.1'	System	10 Sep 2020 23:48:10
	System	10 Sep 2020 23:48:10



US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-10T19:48:03', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'e3fdbbe81-09f8-44ab-9dca-85d408608ba2'	System	10 Sep 2020 23:48:10
User entered 'No (N)'	System	10 Sep 2020 23:48:10

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-10T19:48:08', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'e3fdb81-09f8-44ab-9dca-85d408608ba2'	System	10 Sep 2020 23:48:10
User entered '10 Sep 2020 19:48'	System	10 Sep 2020 23:48:10

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	09 Sep 2020 13:22:53
User entered 'Day 3'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:01:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-11T19:29:13', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'e20abb1d-177c-48db-b512-1764ebc92892' User entered 'Yes (Y)'	System	11 Sep 2020 23:29:33
	System	11 Sep 2020 23:29:33

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:01:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-11T19:29:19', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'e20abb1d-177c-48db-b512-1764ebc92892' User entered '97.9'	System	11 Sep 2020 23:29:33
	System	11 Sep 2020 23:29:33

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-11T19:29:23', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'e20abb1d-177c-48db-b512-1764ebc92892'	System	11 Sep 2020 23:29:33
User entered 'No (N)'	System	11 Sep 2020 23:29:33



US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-11T19:29:28', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'e20abb1d-177c-48db-b512-1764ebc92892'	System	11 Sep 2020 23:29:33
User entered '11 Sep 2020 19:29'	System	11 Sep 2020 23:29:33

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	09 Sep 2020 13:22:53
User entered 'Day 4'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:01:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-12T19:16:58', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'cfc5c820-8505-4b54-8df3-71aa3a495939' User entered 'Yes (Y)'	System	12 Sep 2020 23:17:17
	System	12 Sep 2020 23:17:17

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:01:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-12T19:17:05', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'cfc5c820-8505-4b54-8df3-71aa3a495939' User entered '97.4'	System	12 Sep 2020 23:17:17
	System	12 Sep 2020 23:17:17

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-12T19:17:09', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'cfc5c820-8505-4b54-8df3-71aa3a495939'	System	12 Sep 2020 23:17:17
User entered 'No (N)'	System	12 Sep 2020 23:17:17

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-12T19:17:15', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'cfc5c820-8505-4b54-8df3-71aa3a495939'	System	12 Sep 2020 23:17:17
User entered '12 Sep 2020 19:17'	System	12 Sep 2020 23:17:17



US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	09 Sep 2020 13:22:53
User entered 'Day 5'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:01:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-13T19:16:07', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'b1bce566-2dbd-41ab-86be-653266b87624' User entered 'Yes (Y)'	System	13 Sep 2020 23:16:26
	System	13 Sep 2020 23:16:26

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:01:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-13T19:16:14', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'b1bce566-2dbd-41ab-86be-653266b87624' User entered '97.9'	System	13 Sep 2020 23:16:26
	System	13 Sep 2020 23:16:26

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-13T19:16:19', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'b1bce566-2dbd-41ab-86be-653266b87624'	System	13 Sep 2020 23:16:26
User entered 'No (N)'	System	13 Sep 2020 23:16:26

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-13T19:16:23', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'b1bce566-2dbd-41ab-86be-653266b87624'	System	13 Sep 2020 23:16:26
User entered '13 Sep 2020 19:16'	System	13 Sep 2020 23:16:26

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 13:22:53



US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	09 Sep 2020 13:22:53
User entered 'Day 6'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:01:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-14T19:15:23', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '7a465b3e-ca61-42bb-a585-cfd9ab35129a' User entered 'Yes (Y)'	System	14 Sep 2020 23:15:39
	System	14 Sep 2020 23:15:39

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:01:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-14T19:15:29', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '7a465b3e-ca61-42bb-a585-cfd9ab35129a' User entered '97.6'	System	14 Sep 2020 23:15:39
	System	14 Sep 2020 23:15:39

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-14T19:15:32', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '7a465b3e-ca61-42bb-a585-cfd9ab35129a' User entered 'No (N)'	System	14 Sep 2020 23:15:39
	System	14 Sep 2020 23:15:39

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-14T19:15:37', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '7a465b3e-ca61-42bb-a585-cfd9ab35129a' User entered '14 Sep 2020 19:15'	System	14 Sep 2020 23:15:39
	System	14 Sep 2020 23:15:39

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 13:22:53



US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	09 Sep 2020 13:22:53
User entered 'Day 7'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:01:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-15T20:23:11', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '0ccce9e8-cf73-41c5-bf97-a74479e3c57d'	System	16 Sep 2020 00:23:27
User entered 'Yes (Y)'	System	16 Sep 2020 00:23:27

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:01:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-15T20:23:16', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '0ccce9e8-cf73-41c5-bf97-a74479e3c57d' User entered '97.2'	System	16 Sep 2020 00:23:27
	System	16 Sep 2020 00:23:27

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-15T20:23:19', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '0ccce9e8-cf73-41c5-bf97-a74479e3c57d'	System	16 Sep 2020 00:23:27
User entered 'No (N)'	System	16 Sep 2020 00:23:27

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-15T20:23:22', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '0ccce9e8-cf73-41c5-bf97-a74479e3c57d' User entered '15 Sep 2020 20:23'	System	16 Sep 2020 00:23:27
	System	16 Sep 2020 00:23:27

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	09 Sep 2020 13:22:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 13:22:53



US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-09T09:49:01', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'ffbf55b6-e8ae-45a0-b53b-23ddeefb94c0'	System	09 Sep 2020 13:49:38
User entered 'None (1)'	System	09 Sep 2020 13:49:38

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-09T09:49:17', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'ffbf55b6-e8ae-45a0-b53b-23ddeefb94c0'	System	09 Sep 2020 13:49:38
User entered 'No (N)'	System	09 Sep 2020 13:49:38

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-09T09:49:21', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'ffbf55b6-e8ae-45a0-b53b-23ddeefb94c0'	System	09 Sep 2020 13:49:38
User entered 'No (N)'	System	09 Sep 2020 13:49:38

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-09T09:49:29', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'ffbf55b6-e8ae-45a0-b53b-23ddeefb94c0'	System	09 Sep 2020 13:49:38
User entered 'None (1)'	System	09 Sep 2020 13:49:38

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-09T09:49:32', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'ffbf55b6-e8ae-45a0-b53b-23ddeefb94c0' User entered '09 Sep 2020 09:49'	System	09 Sep 2020 13:49:38
	System	09 Sep 2020 13:49:38

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '09 Sep 2020 09:37'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '09 Sep 2020 12:07'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	09 Sep 2020 13:22:53
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 13:22:53



US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-09T20:52:14', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '5e86a303-fa6c-4574-8a17-502a28741f6d'	System	10 Sep 2020 00:53:23
User entered 'Does not interfere with activity (2)'	System	10 Sep 2020 00:53:23

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-09T20:52:43', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '5e86a303-fa6c-4574-8a17-502a28741f6d' User entered 'No (N)'	System	10 Sep 2020 00:53:23
	System	10 Sep 2020 00:53:23

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-09T20:53:04', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '5e86a303-fa6c-4574-8a17-502a28741f6d' User entered 'No (N)'	System	10 Sep 2020 00:53:23
	System	10 Sep 2020 00:53:23

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-09T20:53:11', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '5e86a303-fa6c-4574-8a17-502a28741f6d' User entered 'None (1)'	System	10 Sep 2020 00:53:23
	System	10 Sep 2020 00:53:23

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-09T20:53:18', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '5e86a303-fa6c-4574-8a17-502a28741f6d' User entered '09 Sep 2020 20:53'	System	10 Sep 2020 00:53:23
	System	10 Sep 2020 00:53:23

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '09 Sep 2020 13:02'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	09 Sep 2020 13:22:53
User entered 'Day 2'	System	09 Sep 2020 13:22:53



US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-10T19:48:18', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '1ab54b3f-b59e-4794-89b3-d3393a8fcbd1'	System	10 Sep 2020 23:49:06
User entered 'Does not interfere with activity (2)'	System	10 Sep 2020 23:49:06

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:01:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-10T19:48:21', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '1ab54b3f-b59e-4794-89b3-d3393a8fcbd1' User entered 'No (N)'	System	10 Sep 2020 23:49:06
	System	10 Sep 2020 23:49:06

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-10T19:48:25', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '1ab54b3f-b59e-4794-89b3-d3393a8fcbd1' User entered 'Yes (Y)'	System	10 Sep 2020 23:49:06
	System	10 Sep 2020 23:49:06

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-10T19:48:48', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '1ab54b3f-b59e-4794-89b3-d3393a8fcbd1' User entered '75'	System	10 Sep 2020 23:49:06
	System	10 Sep 2020 23:49:06

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-10T19:48:57', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '1ab54b3f-b59e-4794-89b3-d3393a8fcbd1' User entered 'None (1)'	System	10 Sep 2020 23:49:06
	System	10 Sep 2020 23:49:06

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-10T19:49:02', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '1ab54b3f-b59e-4794-89b3-d3393a8fcbd1' User entered '10 Sep 2020 19:49'	System	10 Sep 2020 23:49:06
	System	10 Sep 2020 23:49:06

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 13:22:53



US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	09 Sep 2020 13:22:53
User entered 'Day 3'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-11T19:31:24', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '2de3d4e8-a44b-4b04-bf53-83859afa4783'	System	11 Sep 2020 23:31:55
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 23:31:55

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:01:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-11T19:31:27', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '2de3d4e8-a44b-4b04-bf53-83859afa4783' User entered 'No (N)'	System	11 Sep 2020 23:31:55
	System	11 Sep 2020 23:31:55

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-11T19:31:31', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '2de3d4e8-a44b-4b04-bf53-83859afa4783'	System	11 Sep 2020 23:31:55
User entered 'Yes (Y)'	System	11 Sep 2020 23:31:55

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-11T19:31:42', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '2de3d4e8-a44b-4b04-bf53-83859afa4783' User entered '70'	System	11 Sep 2020 23:31:55
	System	11 Sep 2020 23:31:55

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-11T19:31:45', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '2de3d4e8-a44b-4b04-bf53-83859afa4783' User entered 'None (1)'	System	11 Sep 2020 23:31:55
	System	11 Sep 2020 23:31:55

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-11T19:31:52', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '2de3d4e8-a44b-4b04-bf53-83859afa4783'	System	11 Sep 2020 23:31:55
User entered '11 Sep 2020 19:31'	System	11 Sep 2020 23:31:55

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 13:22:53



US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	09 Sep 2020 13:22:53
User entered 'Day 4'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-12T19:17:22', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '015e4be8-57a7-4d2c-a576-901fec3109f5'	System	12 Sep 2020 23:17:53
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 23:17:53

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:01:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-12T19:17:26', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '015e4be8-57a7-4d2c-a576-901fec3109f5' User entered 'No (N)'	System	12 Sep 2020 23:17:53
	System	12 Sep 2020 23:17:53

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-12T19:17:29', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '015e4be8-57a7-4d2c-a576-901fec3109f5' User entered 'Yes (Y)'	System	12 Sep 2020 23:17:53
	System	12 Sep 2020 23:17:53

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-12T19:17:35', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '015e4be8-57a7-4d2c-a576-901fec3109f5' User entered '50'	System	12 Sep 2020 23:17:53
	System	12 Sep 2020 23:17:53

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-12T19:17:43', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '015e4be8-57a7-4d2c-a576-901fec3109f5'	System	12 Sep 2020 23:17:53
User entered 'None (1)'	System	12 Sep 2020 23:17:53

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-12T19:17:49', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '015e4be8-57a7-4d2c-a576-901fec3109f5'	System	12 Sep 2020 23:17:53
User entered '12 Sep 2020 19:17'	System	12 Sep 2020 23:17:53



US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	09 Sep 2020 13:22:53
User entered 'Day 5'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-13T19:16:36', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'de0ef177-2f4a-4e07-8a86-aa516d53b4b8'	System	13 Sep 2020 23:17:23
User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 23:17:23

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-13T19:16:39', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'de0ef177-2f4a-4e07-8a86-aa516d53b4b8'	System	13 Sep 2020 23:17:23
User entered 'No (N)'	System	13 Sep 2020 23:17:23

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-13T19:16:43', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'de0ef177-2f4a-4e07-8a86-aa516d53b4b8' User entered 'Yes (Y)'	System	13 Sep 2020 23:17:23
	System	13 Sep 2020 23:17:23

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-13T19:17:00', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'de0ef177-2f4a-4e07-8a86-aa516d53b4b8' User entered '45'	System	13 Sep 2020 23:17:23
	System	13 Sep 2020 23:17:23

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-13T19:17:07', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'de0ef177-2f4a-4e07-8a86-aa516d53b4b8'	System	13 Sep 2020 23:17:23
User entered 'None (1)'	System	13 Sep 2020 23:17:23



US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-13T19:17:18', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'de0ef177-2f4a-4e07-8a86-aa516d53b4b8'	System	13 Sep 2020 23:17:23
User entered '13 Sep 2020 19:17'	System	13 Sep 2020 23:17:23

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	09 Sep 2020 13:22:53
User entered 'Day 6'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-14T19:15:50', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'f2f19240-fb3f-4c2d-8eab-977b8964c9c6' User entered 'None (1)'	System	14 Sep 2020 23:16:05
	System	14 Sep 2020 23:16:05

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-14T19:15:48', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'f2f19240-fb3f-4c2d-8eab-977b8964c9c6'	System	14 Sep 2020 23:16:05
User entered 'No (N)'	System	14 Sep 2020 23:16:05

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-14T19:15:56', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'f2f19240-fb3f-4c2d-8eab-977b8964c9c6' User entered 'No (N)'	System	14 Sep 2020 23:16:05
	System	14 Sep 2020 23:16:05

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-14T19:16:00', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'f2f19240-fb3f-4c2d-8eab-977b8964c9c6' User entered 'None (1)'	System	14 Sep 2020 23:16:05
	System	14 Sep 2020 23:16:05



US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-14T19:16:03', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'f2f19240-fb3f-4c2d-8eab-977b8964c9c6'	System	14 Sep 2020 23:16:05
User entered '14 Sep 2020 19:16'	System	14 Sep 2020 23:16:05

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	09 Sep 2020 13:22:53
User entered 'Day 7'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-15T20:23:28', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '22dab60a-ac29-4f32-8849-854366fcd949'	System	16 Sep 2020 00:23:51
User entered 'None (1)'	System	16 Sep 2020 00:23:51

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:01:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-15T20:23:31', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '22dab60a-ac29-4f32-8849-854366fcd949' User entered 'No (N)'	System	16 Sep 2020 00:23:51
	System	16 Sep 2020 00:23:51

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-15T20:23:35', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '22dab60a-ac29-4f32-8849-854366fcd949' User entered 'No (N)'	System	16 Sep 2020 00:23:51
	System	16 Sep 2020 00:23:51

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-15T20:23:43', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '22dab60a-ac29-4f32-8849-854366fcd949' User entered 'None (1)'	System	16 Sep 2020 00:23:51
	System	16 Sep 2020 00:23:51



US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:01:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-15T20:23:47', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '22dab60a-ac29-4f32-8849-854366fcd949' User entered '15 Sep 2020 20:23'	System	16 Sep 2020 00:23:51
	System	16 Sep 2020 00:23:51

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	09 Sep 2020 13:22:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-09T09:49:38', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'c5be8a55-493a-4775-adfb-0ae2841152e8' User entered 'None (0)'	System	09 Sep 2020 13:50:04
	System	09 Sep 2020 13:50:04

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-09T09:49:41', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'c5be8a55-493a-4775-adfb-0ae2841152e8' User entered 'None (0)'	System	09 Sep 2020 13:50:04
	System	09 Sep 2020 13:50:04

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-09T09:49:44', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'c5be8a55-493a-4775-adfb-0ae2841152e8' User entered 'None (0)'	System	09 Sep 2020 13:50:04
	System	09 Sep 2020 13:50:04

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-09T09:49:47', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'c5be8a55-493a-4775-adfb-0ae2841152e8' User entered 'None (0)'	System	09 Sep 2020 13:50:04
	System	09 Sep 2020 13:50:04



US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-09T09:49:50', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'c5be8a55-493a-4775-adfb-0ae2841152e8' User entered 'None (0)'	System	09 Sep 2020 13:50:04
	System	09 Sep 2020 13:50:04

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-09T09:49:52', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'c5be8a55-493a-4775-adfb-0ae2841152e8' User entered 'None (0)'	System	09 Sep 2020 13:50:04
	System	09 Sep 2020 13:50:04

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-09T09:49:56', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'c5be8a55-493a-4775-adfb-0ae2841152e8' User entered 'No (N)'	System	09 Sep 2020 13:50:04
	System	09 Sep 2020 13:50:04

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-09T09:50:00', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'c5be8a55-493a-4775-adfb-0ae2841152e8' User entered '09 Sep 2020 09:50'	System	09 Sep 2020 13:50:04
	System	09 Sep 2020 13:50:04

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '09 Sep 2020 09:37'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '09 Sep 2020 12:07'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	09 Sep 2020 13:22:53
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-09T20:53:24', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'c0ff88d5-c455-4f16-b984-a724489325a8' User entered 'None (0)'	System	10 Sep 2020 00:53:53
	System	10 Sep 2020 00:53:53



US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-09T20:53:28', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'c0ff88d5-c455-4f16-b984-a724489325a8' User entered 'None (0)'	System	10 Sep 2020 00:53:53
	System	10 Sep 2020 00:53:53

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-09T20:53:32', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'c0ff88d5-c455-4f16-b984-a724489325a8' User entered 'None (0)'	System	10 Sep 2020 00:53:53
	System	10 Sep 2020 00:53:53

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-09T20:53:35', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'c0ff88d5-c455-4f16-b984-a724489325a8' User entered 'None (0)'	System	10 Sep 2020 00:53:53
	System	10 Sep 2020 00:53:53

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-09T20:53:38', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'c0ff88d5-c455-4f16-b984-a724489325a8' User entered 'None (0)'	System	10 Sep 2020 00:53:53
	System	10 Sep 2020 00:53:53

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-09T20:53:42', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'c0ff88d5-c455-4f16-b984-a724489325a8' User entered 'None (0)'	System	10 Sep 2020 00:53:53
	System	10 Sep 2020 00:53:53

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-09T20:53:46', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'c0ff88d5-c455-4f16-b984-a724489325a8' User entered 'No (N)'	System	10 Sep 2020 00:53:53
	System	10 Sep 2020 00:53:53

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-09T20:53:51', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'c0ff88d5-c455-4f16-b984-a724489325a8' User entered '09 Sep 2020 20:53'	System	10 Sep 2020 00:53:53
	System	10 Sep 2020 00:53:53

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '09 Sep 2020 13:02'	System	09 Sep 2020 13:22:53



US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	09 Sep 2020 13:22:53
User entered 'Day 2'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:01:20

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-10T19:49:16', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '846ec817-0e80-4e61-b5b3-48d288c4b21a'	System	10 Sep 2020 23:49:48
User entered 'No interference with activity (1)'	System	10 Sep 2020 23:49:48

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:01:20

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-10T19:49:25', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '846ec817-0e80-4e61-b5b3-48d288c4b21a' User entered 'None (0)'	System	10 Sep 2020 23:49:48
	System	10 Sep 2020 23:49:48

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:01:20

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-10T19:49:29', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '846ec817-0e80-4e61-b5b3-48d288c4b21a' User entered 'None (0)'	System	10 Sep 2020 23:49:48
	System	10 Sep 2020 23:49:48

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:01:20

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-10T19:49:32', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '846ec817-0e80-4e61-b5b3-48d288c4b21a' User entered 'None (0)'	System	10 Sep 2020 23:49:48
	System	10 Sep 2020 23:49:48

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:01:20

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-10T19:49:37', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '846ec817-0e80-4e61-b5b3-48d288c4b21a' User entered 'None (0)'	System	10 Sep 2020 23:49:48
	System	10 Sep 2020 23:49:48

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:01:20

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-10T19:49:40', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '846ec817-0e80-4e61-b5b3-48d288c4b21a' User entered 'None (0)'	System	10 Sep 2020 23:49:48
	System	10 Sep 2020 23:49:48



US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-10T19:49:43', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '846ec817-0e80-4e61-b5b3-48d288c4b21a' User entered 'No (N)'	System	10 Sep 2020 23:49:48
	System	10 Sep 2020 23:49:48

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:01:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-10T19:49:46', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '846ec817-0e80-4e61-b5b3-48d288c4b21a' User entered '10 Sep 2020 19:49'	System	10 Sep 2020 23:49:48
	System	10 Sep 2020 23:49:48

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	09 Sep 2020 13:22:53
User entered 'Day 3'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:01:20

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-11T19:32:00', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '882fc5d5-b588-469f-a06b-96863f118825'	System	11 Sep 2020 23:32:38
User entered 'No interference with activity (1)'	System	11 Sep 2020 23:32:38

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:01:20

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-11T19:32:12', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '882fc5d5-b588-469f-a06b-96863f118825' User entered 'None (0)'	System	11 Sep 2020 23:32:38
	System	11 Sep 2020 23:32:38

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:01:20

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-11T19:32:16', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '882fc5d5-b588-469f-a06b-96863f118825' User entered 'None (0)'	System	11 Sep 2020 23:32:38
	System	11 Sep 2020 23:32:38



US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:01:20

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-11T19:32:19', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '882fc5d5-b588-469f-a06b-96863f118825' User entered 'None (0)'	System	11 Sep 2020 23:32:38
	System	11 Sep 2020 23:32:38

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:01:20

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-11T19:32:22', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '882fc5d5-b588-469f-a06b-96863f118825' User entered 'None (0)'	System	11 Sep 2020 23:32:38
	System	11 Sep 2020 23:32:38

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:01:20

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-11T19:32:25', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '882fc5d5-b588-469f-a06b-96863f118825' User entered 'None (0)'	System	11 Sep 2020 23:32:38
	System	11 Sep 2020 23:32:38

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-11T19:32:28', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '882fc5d5-b588-469f-a06b-96863f118825' User entered 'No (N)'	System	11 Sep 2020 23:32:38
	System	11 Sep 2020 23:32:38

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:01:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-11T19:32:35', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '882fc5d5-b588-469f-a06b-96863f118825'	System	11 Sep 2020 23:32:38
User entered '11 Sep 2020 19:32'	System	11 Sep 2020 23:32:38

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	09 Sep 2020 13:22:53
User entered 'Day 4'	System	09 Sep 2020 13:22:53



US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:01:20

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-12T19:17:57', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '5da19919-b568-408b-943b-a501a93ccfb3'	System	12 Sep 2020 23:18:25
User entered 'No interference with activity (1)'	System	12 Sep 2020 23:18:25

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:01:20

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-12T19:18:03', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '5da19919-b568-408b-943b-a501a93ccfb3' User entered 'None (0)'	System	12 Sep 2020 23:18:25
	System	12 Sep 2020 23:18:25

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:01:20

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-12T19:18:06', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '5da19919-b568-408b-943b-a501a93ccfb3' User entered 'None (0)'	System	12 Sep 2020 23:18:25
	System	12 Sep 2020 23:18:25

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:01:20

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-12T19:18:09', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '5da19919-b568-408b-943b-a501a93ccfb3' User entered 'None (0)'	System	12 Sep 2020 23:18:25
	System	12 Sep 2020 23:18:25

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:01:20

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-12T19:18:12', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '5da19919-b568-408b-943b-a501a93ccfb3' User entered 'None (0)'	System	12 Sep 2020 23:18:25
	System	12 Sep 2020 23:18:25

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:01:20

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-12T19:18:15', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '5da19919-b568-408b-943b-a501a93ccfb3' User entered 'None (0)'	System	12 Sep 2020 23:18:25
	System	12 Sep 2020 23:18:25

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-12T19:18:19', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '5da19919-b568-408b-943b-a501a93ccfb3' User entered 'No (N)'	System	12 Sep 2020 23:18:25
	System	12 Sep 2020 23:18:25

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:01:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-12T19:18:23', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '5da19919-b568-408b-943b-a501a93ccfb3' User entered '12 Sep 2020 19:18'	System	12 Sep 2020 23:18:25
	System	12 Sep 2020 23:18:25



US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	09 Sep 2020 13:22:53
User entered 'Day 5'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:01:20

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-13T19:17:25', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'd2ffda8-f85b-40e7-af78-0ce04398bd43'	System	13 Sep 2020 23:18:02
User entered 'No interference with activity (1)'	System	13 Sep 2020 23:18:02

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:01:20

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-13T19:17:31', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'd2ffda8-f85b-40e7-af78-0ce04398bd43' User entered 'None (0)'	System	13 Sep 2020 23:18:02
	System	13 Sep 2020 23:18:02

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:01:20

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-13T19:17:35', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'd2ffda8-f85b-40e7-af78-0ce04398bd43' User entered 'None (0)'	System	13 Sep 2020 23:18:02
	System	13 Sep 2020 23:18:02

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:01:20

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-13T19:17:38', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'd2ffda8-f85b-40e7-af78-0ce04398bd43' User entered 'None (0)'	System	13 Sep 2020 23:18:02
	System	13 Sep 2020 23:18:02

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:01:20

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-13T19:17:41', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'd2ffda8-f85b-40e7-af78-0ce04398bd43' User entered 'None (0)'	System	13 Sep 2020 23:18:02
	System	13 Sep 2020 23:18:02



US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:01:20

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-13T19:17:44', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'd2ffda8-f85b-40e7-af78-0ce04398bd43' User entered 'None (0)'	System	13 Sep 2020 23:18:02
	System	13 Sep 2020 23:18:02

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-13T19:17:50', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'd2ffda8-f85b-40e7-af78-0ce04398bd43'	System	13 Sep 2020 23:18:02
User entered 'No (N)'	System	13 Sep 2020 23:18:02

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:01:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-13T19:17:58', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'd2ffda8-f85b-40e7-af78-0ce04398bd43'	System	13 Sep 2020 23:18:02
User entered '13 Sep 2020 19:17'	System	13 Sep 2020 23:18:02

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	09 Sep 2020 13:22:53
User entered 'Day 6'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:01:20

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-14T19:16:09', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'fd659349-5e2c-49f4-91b5-3ee72ca8de4f' User entered 'None (0)'	System	14 Sep 2020 23:16:35
	System	14 Sep 2020 23:16:35

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:01:20

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-14T19:16:12', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'fd659349-5e2c-49f4-91b5-3ee72ca8de4f' User entered 'None (0)'	System	14 Sep 2020 23:16:35
	System	14 Sep 2020 23:16:35



US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:01:20

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-14T19:16:15', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'fd659349-5e2c-49f4-91b5-3ee72ca8de4f' User entered 'None (0)'	System	14 Sep 2020 23:16:35
	System	14 Sep 2020 23:16:35

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:01:20

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-14T19:16:18', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'fd659349-5e2c-49f4-91b5-3ee72ca8de4f' User entered 'None (0)'	System	14 Sep 2020 23:16:35
	System	14 Sep 2020 23:16:35

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:01:20

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-14T19:16:21', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'fd659349-5e2c-49f4-91b5-3ee72ca8de4f' User entered 'None (0)'	System	14 Sep 2020 23:16:35
	System	14 Sep 2020 23:16:35

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:01:20

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-14T19:16:24', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'fd659349-5e2c-49f4-91b5-3ee72ca8de4f' User entered 'None (0)'	System	14 Sep 2020 23:16:35
	System	14 Sep 2020 23:16:35

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-14T19:16:27', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'fd659349-5e2c-49f4-91b5-3ee72ca8de4f' User entered 'No (N)'	System	14 Sep 2020 23:16:35
	System	14 Sep 2020 23:16:35

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:01:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-14T19:16:30', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'fd659349-5e2c-49f4-91b5-3ee72ca8de4f' User entered '14 Sep 2020 19:16'	System	14 Sep 2020 23:16:35
	System	14 Sep 2020 23:16:35

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 13:22:53



US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	09 Sep 2020 13:22:53
User entered 'Day 7'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:01:20

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-15T20:23:51', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '8722eca4-4369-43ac-a12e-b8b6649427d3' User entered 'None (0)'	System	16 Sep 2020 00:24:15
	System	16 Sep 2020 00:24:15

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:01:20

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-15T20:23:54', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '8722eca4-4369-43ac-a12e-b8b6649427d3' User entered 'None (0)'	System	16 Sep 2020 00:24:15
	System	16 Sep 2020 00:24:15

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:01:20

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-15T20:23:57', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '8722eca4-4369-43ac-a12e-b8b6649427d3' User entered 'None (0)'	System	16 Sep 2020 00:24:15
	System	16 Sep 2020 00:24:15

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:01:20

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-15T20:24:00', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '8722eca4-4369-43ac-a12e-b8b6649427d3' User entered 'None (0)'	System	16 Sep 2020 00:24:15
	System	16 Sep 2020 00:24:15

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:01:20

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-15T20:24:03', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '8722eca4-4369-43ac-a12e-b8b6649427d3' User entered 'None (0)'	System	16 Sep 2020 00:24:15
	System	16 Sep 2020 00:24:15

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:01:20

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-15T20:24:05', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '8722eca4-4369-43ac-a12e-b8b6649427d3' User entered 'None (0)'	System	16 Sep 2020 00:24:15
	System	16 Sep 2020 00:24:15

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-15T20:24:09', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '8722eca4-4369-43ac-a12e-b8b6649427d3' User entered 'No (N)'	System	16 Sep 2020 00:24:15
	System	16 Sep 2020 00:24:15



US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:01:20

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-09-15T20:24:12', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '8722eca4-4369-43ac-a12e-b8b6649427d3' User entered '15 Sep 2020 20:24'	System	16 Sep 2020 00:24:15
	System	16 Sep 2020 00:24:15

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:01:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 13:22:53

US3832055

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:01:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 13:22:53

US3832055

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 02:07:41
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:03:21
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 19:10:48

US3832055

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:07:41
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:03:21
User entered '16 Sep 2020'	Alyssa-Kay Peay (b) (4)	16 Sep 2020 19:10:48

US3832055

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 02:07:41
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:03:21
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 19:10:48

US3832055

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 02:07:41
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:03:21
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 19:10:48

US3832055

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:01:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 02:07:45
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:03:27
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 19:10:53



US3832055

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:01:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered 'I'	System	16 Sep 2020 19:10:53

US3832055

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:07:54
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:03:57
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	23 Sep 2020 21:00:58

US3832055

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 02:07:54
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:03:57
User entered '23 Sep 2020'	Alyssa-Kay Peay (b) (4)	23 Sep 2020 21:00:58

US3832055

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 02:07:54
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:03:57
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4) (b) (4)	23 Sep 2020 21:00:58

US3832055

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 02:07:54
DataPoint Verified.	(b) (4), (b) (6)	29 Sep 2020 19:03:57
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	23 Sep 2020 21:00:58

US3832055

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:01:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	23 Sep 2020 21:01:02

US3832055

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:01:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered 'I'	System	23 Sep 2020 21:01:02

US3832055

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	01 Oct 2020 17:00:22



US3832055

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User entered '1 Oct 2020'	(b) (4) Alyssa-Kay Peay (b) (4)	01 Oct 2020 17:00:22

US3832055

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alyssa-Kay Peay (b) (4)	01 Oct 2020 17:00:22

US3832055

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User entered empty.	Alyssa-Kay Peay (b) (4)	01 Oct 2020 17:00:22

US3832055

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:01:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:10
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	01 Oct 2020 17:00:27

US3832055

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:01:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered 'I'	System	01 Oct 2020 17:00:27

US3832055

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:01:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:21
User entered 'Yes (Y)'	Emma Partin (b) (4)	07 Oct 2020 14:35:22

US3832055

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:21
User entered '7 Oct 2020'	(b) (4) Emma Partin (b) (4)	07 Oct 2020 14:35:22

US3832055

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:01:20

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:21
User entered 'Clinic (Clinic)'	Emma Partin (b) (4)	07 Oct 2020 14:35:22



US3832055

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:01:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered 'VISIT3'	System	07 Oct 2020 14:35:22

US3832055

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:21
User entered 'Yes (Y)'	(b) (4) Emma Partin (b) (4)	07 Oct 2020 14:35:58

US3832055

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:21
User entered '7 Oct 2020'	(b) (4) Emma Partin (b) (4)	07 Oct 2020 14:35:58

US3832055

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:21
User entered '10:05'	(b) (4)	
	Emma Partin (b) (4)	07 Oct 2020 14:35:58
	(b) (4)	

US3832055

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered '7 Oct 2020 10:05'	System	07 Oct 2020 14:35:58

US3832055

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:21
User entered '98.2' F	Emma Partin (b) (4)	07 Oct 2020 14:35:58

US3832055

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:21
User entered 'Oral (Oral)'	Emma Partin (b) (4)	07 Oct 2020 14:35:58

US3832055

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:21
User entered empty.	Emma Partin (b) (4)	07 Oct 2020 14:35:58



US3832055

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:21
User entered '66'	Emma Partin (b) (4)	07 Oct 2020 14:35:58

US3832055

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered 'bpm'	System	07 Oct 2020 14:35:58

US3832055

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:21
User entered '14'	Emma Partin (b) (4)	07 Oct 2020 14:35:58

US3832055

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered 'breaths/min'	System	07 Oct 2020 14:35:58

US3832055

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:21
User entered '160'	Emma Partin (b) (4)	07 Oct 2020 14:35:58

US3832055

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered 'mmHg'	System	07 Oct 2020 14:35:58

US3832055

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:21
User entered '87'	Emma Partin (b) (4)	07 Oct 2020 14:35:58

US3832055

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered 'mmHg'	System	07 Oct 2020 14:35:58



US3832055

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16

US3832055

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16

US3832055

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:01:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:21
User entered 'Yes (Y)'	(b) (4) Emma Partin (b) (4)	07 Oct 2020 14:41:11

US3832055

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:01:20

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:21
User entered '7 Oct 2020'	Emma Partin (b) (4)	07 Oct 2020 14:41:11

US3832055

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:01:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:21
User entered 'Yes (Y)'	Emma Partin (b) (4)	07 Oct 2020 14:41:27

US3832055

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:01:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:21
User entered '7 Oct 2020'	Emma Partin (b) (4)	07 Oct 2020 14:41:27

US3832055

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:01:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:21
User entered '10:20'	Emma Partin (b) (4)	07 Oct 2020 14:41:27

US3832055

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:01:20

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered '7 Oct 2020 10:20'	System	07 Oct 2020 14:41:27



US3832055

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:01:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:02:21
User entered 'Yes (Y)'	Emma Partin (b) (4)	07 Oct 2020 14:41:31

US3832055

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:01:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered 'I'	System	07 Oct 2020 14:41:31

US3832055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered 'Day 64'	System	03 Aug 2020 15:36:39

US3832055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

[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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-10-07T10:06:28', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'e1c18b71-f9c5-40e1-be60-e5391394336f' User entered 'No (N)'	System	07 Oct 2020 14:06:39
	System	07 Oct 2020 14:06:39

US3832055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

Have you been exposed to someone with 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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-10-07T10:06:34', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'e1c18b71-f9c5-40e1-be60-e5391394336f' User entered 'No (N)'	System	07 Oct 2020 14:06:39
	System	07 Oct 2020 14:06:39

US3832055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-10-07T10:06:37', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'e1c18b71-f9c5-40e1-be60-e5391394336f' User entered '07 Oct 2020 10:06:37'	System	07 Oct 2020 14:06:39
	System	07 Oct 2020 14:06:39

US3832055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered '03 Oct 2020 00:01'	System	03 Aug 2020 15:36:39

US3832055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered '07 Oct 2020 23:59'	System	03 Aug 2020 15:36:39



US3832055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered 'Day 71'	System	03 Aug 2020 15:36:39

US3832055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-10-11T19:22:41', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'e40d471d-8f39-4d4e-a57f-2aa956668326'	System	11 Oct 2020 23:22:55
User entered 'No (N)'	System	11 Oct 2020 23:22:55

US3832055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

Have you been exposed to someone with 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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-10-11T19:22:46', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'e40d471d-8f39-4d4e-a57f-2aa956668326'	System	11 Oct 2020 23:22:55
User entered 'No (N)'	System	11 Oct 2020 23:22:55

US3832055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-10-11T19:22:52', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'e40d471d-8f39-4d4e-a57f-2aa956668326' User entered '11 Oct 2020 19:22:52'	System	11 Oct 2020 23:22:55
	System	11 Oct 2020 23:22:55

US3832055

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered '10 Oct 2020 00:01'	System	03 Aug 2020 15:36:39

US3832055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered '14 Oct 2020 23:59'	System	03 Aug 2020 15:36:39

US3832055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered 'Day 78'	System	03 Aug 2020 15:36:39

US3832055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

[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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-10-19T08:59:04', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'e8f33e33-715c-4696-a955-b96ac654a296'	System	19 Oct 2020 12:59:22
User entered 'No (N)'	System	19 Oct 2020 12:59:22



US3832055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

Have you been exposed to someone with 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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-10-19T08:59:14', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'e8f33e33-715c-4696-a955-b96ac654a296'	System	19 Oct 2020 12:59:22
User entered 'No (N)'	System	19 Oct 2020 12:59:22

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-10-19T08:59:20', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'e8f33e33-715c-4696-a955-b96ac654a296'	System	19 Oct 2020 12:59:22
User entered '19 Oct 2020 08:59:20'	System	19 Oct 2020 12:59:22

US3832055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered '17 Oct 2020 00:01'	System	03 Aug 2020 15:36:39

US3832055

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered '21 Oct 2020 23:59'	System	03 Aug 2020 15:36:39

US3832055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered 'Day 92'	System	03 Aug 2020 15:36:39

US3832055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-10-31T12:40:35', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'f358bdb7-537b-42db-b731-64257fda16a0' User entered 'No (N)'	System	05 Nov 2020 18:30:38
	System	05 Nov 2020 18:30:38

US3832055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

Have you been exposed to someone with 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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-10-31T12:40:40', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'f358bdb7-537b-42db-b731-64257fda16a0' User entered 'No (N)'	System	05 Nov 2020 18:30:38
	System	05 Nov 2020 18:30:38

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-10-31T12:40:45', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'f358bdb7-537b-42db-b731-64257fda16a0' User entered '31 Oct 2020 12:40:45'	System	05 Nov 2020 18:30:38
	System	05 Nov 2020 18:30:38



US3832055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered '31 Oct 2020 00:01'	System	03 Aug 2020 15:36:39

US3832055

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered '04 Nov 2020 23:59'	System	03 Aug 2020 15:36:39

US3832055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered 'Day 99'	System	03 Aug 2020 15:36:39

US3832055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

[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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-11-08T08:13:46', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'fa71c9ee-c020-49f4-800f-722cecd42875'	System	08 Nov 2020 13:14:00
User entered 'No (N)'	System	08 Nov 2020 13:14:00

US3832055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

Have you been exposed to someone with 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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-11-08T08:13:50', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'fa71c9ee-c020-49f4-800f-722cecd42875'	System	08 Nov 2020 13:14:00
User entered 'No (N)'	System	08 Nov 2020 13:14:00

US3832055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-11-08T08:13:58', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'fa71c9ee-c020-49f4-800f-722cecd42875' User entered '08 Nov 2020 08:13:58'	System	08 Nov 2020 13:14:00
	System	08 Nov 2020 13:14:00

US3832055

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered '07 Nov 2020 00:01'	System	03 Aug 2020 15:36:39

US3832055

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered '11 Nov 2020 23:59'	System	03 Aug 2020 15:36:39



US3832055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered 'Day 106'	System	03 Aug 2020 15:36:39

US3832055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-11-15T17:49:56', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '7f04443d-f4d8-42a8-b353-94184e2a014a'	System	15 Nov 2020 22:50:08
User entered 'No (N)'	System	15 Nov 2020 22:50:08

US3832055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

Have you been exposed to someone with 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 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-11-15T17:50:00', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '7f04443d-f4d8-42a8-b353-94184e2a014a'	System	15 Nov 2020 22:50:08
User entered 'No (N)'	System	15 Nov 2020 22:50:08

US3832055

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-11-15T17:50:04', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '7f04443d-f4d8-42a8-b353-94184e2a014a' User entered '15 Nov 2020 17:50:04'	System	15 Nov 2020 22:50:08
	System	15 Nov 2020 22:50:08

US3832055

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered '14 Nov 2020 00:01'	System	03 Aug 2020 15:36:39

US3832055

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:26:14
Data entry locked.	System	03 Aug 2020 15:36:39
User entered '18 Nov 2020 23:59'	System	03 Aug 2020 15:36:39

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-11-22T09:51:47', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '3c696497-e703-43c1-8d61-9bcf4bb57592'	System	22 Nov 2020 14:52:07
User entered 'No (N)'	System	22 Nov 2020 14:52:07



**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Have you been exposed to someone with 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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-11-22T09:51:58', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '3c696497-e703-43c1-8d61-9bcf4bb57592'	System	22 Nov 2020 14:52:07
User entered 'No (N)'	System	22 Nov 2020 14:52:07

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-11-22T09:52:05', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '3c696497-e703-43c1-8d61-9bcf4bb57592' User entered '22 Nov 2020 09:52:05'	System	22 Nov 2020 14:52:07
	System	22 Nov 2020 14:52:07

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-11-29T14:40:37', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'a3d5faca-da31-4e11-bb08-2c5538bfad68'	System	29 Nov 2020 19:40:53
User entered 'No (N)'	System	29 Nov 2020 19:40:53

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

Have you been exposed to someone with 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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-11-29T14:40:48', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'a3d5faca-da31-4e11-bb08-2c5538bfad68'	System	29 Nov 2020 19:40:53
User entered 'No (N)'	System	29 Nov 2020 19:40:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-11-29T14:40:51', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'a3d5faca-da31-4e11-bb08-2c5538bfad68' User entered '29 Nov 2020 14:40:51'	System	29 Nov 2020 19:40:53
	System	29 Nov 2020 19:40:53



**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-12-06T16:00:03', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '739c0ab2-4ff4-4168-b3ac-388e4b7a5644'	System	06 Dec 2020 21:00:12
User entered 'No (N)'	System	06 Dec 2020 21:00:12

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

Have you been exposed to someone with 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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-12-06T16:00:06', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '739c0ab2-4ff4-4168-b3ac-388e4b7a5644'	System	06 Dec 2020 21:00:12
User entered 'No (N)'	System	06 Dec 2020 21:00:12

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-12-06T16:00:09', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '739c0ab2-4ff4-4168-b3ac-388e4b7a5644' User entered '06 Dec 2020 16:00:09'	System	06 Dec 2020 21:00:12
	System	06 Dec 2020 21:00:12

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 11:41:53



**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-12-09T17:31:48', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '1723104e-afdd-4580-9f18-491509566d69' User entered 'No (N)'	System	09 Dec 2020 22:31:56
	System	09 Dec 2020 22:31:56

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

Have you been exposed to someone with 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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-12-09T17:31:51', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '1723104e-afdd-4580-9f18-491509566d69' User entered 'No (N)'	System	09 Dec 2020 22:31:56
	System	09 Dec 2020 22:31:56

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-12-09T17:31:54', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '1723104e-afdd-4580-9f18-491509566d69' User entered '09 Dec 2020 17:31:54'	System	09 Dec 2020 22:31:56
	System	09 Dec 2020 22:31:56

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-12-16T07:38:08', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'b4bd1f73-c54e-4bbc-bb48-78978fe67267'	System	16 Dec 2020 12:39:32
User entered 'No (N)'	System	16 Dec 2020 12:39:32



US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

Have you been exposed to someone with 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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-12-16T07:38:18', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'b4bd1f73-c54e-4bbc-bb48-78978fe67267'	System	16 Dec 2020 12:39:32
User entered 'No (N)'	System	16 Dec 2020 12:39:32

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-12-16T07:38:23', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'b4bd1f73-c54e-4bbc-bb48-78978fe67267' User entered '16 Dec 2020 07:38:23'	System	16 Dec 2020 12:39:32
	System	16 Dec 2020 12:39:32

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-12-23T10:59:29', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '2717298c-30f1-42b2-949f-324e6b69725e' User entered 'No (N)'	System	23 Dec 2020 15:59:42
	System	23 Dec 2020 15:59:42

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

Have you been exposed to someone with 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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-12-23T10:59:35', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '2717298c-30f1-42b2-949f-324e6b69725e' User entered 'No (N)'	System	23 Dec 2020 15:59:42
	System	23 Dec 2020 15:59:42

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-12-23T10:59:39', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '2717298c-30f1-42b2-949f-324e6b69725e' User entered '23 Dec 2020 10:59:39'	System	23 Dec 2020 15:59:42
	System	23 Dec 2020 15:59:42



**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-12-30T13:32:40', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '0258d6e7-b491-4e69-9faf-bed06c6ab1b5' User entered 'No (N)'	System	08 Jan 2021 22:19:46
	System	08 Jan 2021 22:19:46

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

Have you been exposed to someone with 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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-12-30T13:32:45', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '0258d6e7-b491-4e69-9faf-bed06c6ab1b5' User entered 'No (N)'	System	08 Jan 2021 22:19:46

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2020-12-30T13:32:50', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '0258d6e7-b491-4e69-9faf-bed06c6ab1b5' User entered '30 Dec 2020 13:32:50'	System	08 Jan 2021 22:19:46

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 11:41:53



**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-01-08T17:19:51', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'cba247ae-2185-4ac3-82da-881471cab76e' User entered 'No (N)'	System	08 Jan 2021 22:20:01
	System	08 Jan 2021 22:20:01

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

Have you been exposed to someone with 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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-01-08T17:19:55', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'cba247ae-2185-4ac3-82da-881471cab76e' User entered 'No (N)'	System	08 Jan 2021 22:20:01

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-01-08T17:19:58', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'cba247ae-2185-4ac3-82da-881471cab76e' User entered '08 Jan 2021 17:19:58'	System	08 Jan 2021 22:20:01
	System	08 Jan 2021 22:20:01

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-01-15T11:47:30', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '35f83018-4dc9-4026-82c9-1072c08ea8f7'	System	15 Jan 2021 16:47:44
User entered 'No (N)'	System	15 Jan 2021 16:47:44



**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Have you been exposed to someone with 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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-01-15T11:47:34', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '35f83018-4dc9-4026-82c9-1072c08ea8f7'	System	15 Jan 2021 16:47:44
User entered 'No (N)'	System	15 Jan 2021 16:47:44

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-01-15T11:47:38', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '35f83018-4dc9-4026-82c9-1072c08ea8f7' User entered '15 Jan 2021 11:47:38'	System	15 Jan 2021 16:47:44
	System	15 Jan 2021 16:47:44

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 11:41:53

US3832055

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-01-20T11:06:34', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '6c21b4af-0bdf-4225-9bf4-1bdd7b684571' User entered 'No (N)'	System	20 Jan 2021 16:06:55
	System	20 Jan 2021 16:06:55

US3832055

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

Have you been exposed to someone with 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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-01-20T11:06:44', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '6c21b4af-0bdf-4225-9bf4-1bdd7b684571' User entered 'No (N)'	System	20 Jan 2021 16:06:55
	System	20 Jan 2021 16:06:55

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-01-20T11:06:48', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '6c21b4af-0bdf-4225-9bf4-1bdd7b684571' User entered '20 Jan 2021 11:06:48'	System	20 Jan 2021 16:06:55
	System	20 Jan 2021 16:06:55



**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-01-27T08:00:14', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '76c01e27-944c-4845-a0fd-e8c6ef0ca47d'	System	27 Jan 2021 13:00:29
User entered 'No (N)'	System	27 Jan 2021 13:00:29

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

Have you been exposed to someone with 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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-01-27T08:00:22', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '76c01e27-944c-4845-a0fd-e8c6ef0ca47d'	System	27 Jan 2021 13:00:29
User entered 'No (N)'	System	27 Jan 2021 13:00:29

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-01-27T08:00:25', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '76c01e27-944c-4845-a0fd-e8c6ef0ca47d' User entered '27 Jan 2021 08:00:25'	System	27 Jan 2021 13:00:29

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 11:41:53



**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-02-04T13:08:37', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '58f56e5b-183f-46f4-8c6c-245df561b6b7'	System	04 Feb 2021 18:08:54
User entered 'No (N)'	System	04 Feb 2021 18:08:54

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

Have you been exposed to someone with 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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-02-04T13:08:42', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '58f56e5b-183f-46f4-8c6c-245df561b6b7'	System	04 Feb 2021 18:08:54
User entered 'No (N)'	System	04 Feb 2021 18:08:54

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-02-04T13:08:45', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '58f56e5b-183f-46f4-8c6c-245df561b6b7'	System	04 Feb 2021 18:08:54
User entered '04 Feb 2021 13:08:45'	System	04 Feb 2021 18:08:54

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-02-10T08:32:07', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '0ac84361-cb13-4332-b703-5a756fa62db1' User entered 'No (N)'	System	10 Feb 2021 13:32:19
	System	10 Feb 2021 13:32:19



US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

Have you been exposed to someone with 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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-02-10T08:32:11', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '0ac84361-cb13-4332-b703-5a756fa62db1' User entered 'No (N)'	System	10 Feb 2021 13:32:19
	System	10 Feb 2021 13:32:19

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-02-10T08:32:14', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '0ac84361-cb13-4332-b703-5a756fa62db1' User entered '10 Feb 2021 08:32:14'	System	10 Feb 2021 13:32:19
	System	10 Feb 2021 13:32:19

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-02-17T02:23:03', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '55e8d83d-9e6a-4b3a-95f1-40748f6b2459'	System	17 Feb 2021 07:23:16
User entered 'No (N)'	System	17 Feb 2021 07:23:16

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

Have you been exposed to someone with 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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-02-17T02:23:10', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '55e8d83d-9e6a-4b3a-95f1-40748f6b2459' User entered 'No (N)'	System	17 Feb 2021 07:23:16
	System	17 Feb 2021 07:23:16

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-02-17T02:23:13', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '55e8d83d-9e6a-4b3a-95f1-40748f6b2459' User entered '17 Feb 2021 02:23:13'	System	17 Feb 2021 07:23:16
	System	17 Feb 2021 07:23:16



**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-02-24T16:52:54', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '728062b0-440a-492c-925c-27c87b0dd89e' User entered 'No (N)'	System	24 Feb 2021 21:58:27
	System	24 Feb 2021 21:58:27

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

Have you been exposed to someone with 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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-02-24T16:52:58', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '728062b0-440a-492c-925c-27c87b0dd89e' User entered 'No (N)'	System	24 Feb 2021 21:58:27
	System	24 Feb 2021 21:58:27

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-02-24T16:53:01', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '728062b0-440a-492c-925c-27c87b0dd89e' User entered '24 Feb 2021 16:53:01'	System	24 Feb 2021 21:58:27
	System	24 Feb 2021 21:58:27

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 11:41:53



**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-03-04T11:38:41-05:00', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'd0724619-1562-454b-a981-c9a774f3bb61'	System	04 Mar 2021 16:38:56
User entered 'No (N)'	System	04 Mar 2021 16:38:56

US3832055

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

Have you been exposed to someone with 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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-03-04T11:38:47-05:00', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'd0724619-1562-454b-a981-c9a774f3bb61'	System	04 Mar 2021 16:38:56
User entered 'No (N)'	System	04 Mar 2021 16:38:56

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-03-04T11:38:50-05:00', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'd0724619-1562-454b-a981-c9a774f3bb61'	System	04 Mar 2021 16:38:56
User entered '04 Mar 2021 11:38:50'	System	04 Mar 2021 16:38:56

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 11:41:53

US3832055

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-03-10T10:39:30-05:00', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '278c2bad-1626-439f-88b9-77007177ff02'	System	10 Mar 2021 15:39:48
User entered 'No (N)'	System	10 Mar 2021 15:39:48



US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

Have you been exposed to someone with 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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-03-10T10:39:33-05:00', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '278c2bad-1626-439f-88b9-77007177ff02'	System	10 Mar 2021 15:39:48
User entered 'No (N)'	System	10 Mar 2021 15:39:48

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-03-10T10:39:37-05:00', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '278c2bad-1626-439f-88b9-77007177ff02'	System	10 Mar 2021 15:39:48
User entered '10 Mar 2021 10:39:37'	System	10 Mar 2021 15:39:48

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-03-17T08:31:48-04:00', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '6915067f-260b-4dfb-ba50-da10bb681b54'	System	17 Mar 2021 12:32:07
User entered 'No (N)'	System	17 Mar 2021 12:32:07

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

Have you been exposed to someone with 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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-03-17T08:31:54-04:00', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '6915067f-260b-4dfb-ba50-da10bb681b54'	System	17 Mar 2021 12:32:07
User entered 'No (N)'	System	17 Mar 2021 12:32:07

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-03-17T08:32:04-04:00', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '6915067f-260b-4dfb-ba50-da10bb681b54'	System	17 Mar 2021 12:32:07
User entered '17 Mar 2021 08:32:04'	System	17 Mar 2021 12:32:07



**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-03-24T11:49:50-04:00', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '8cab3d70-3e36-4127-a600-81d14b6e61cd'	System	24 Mar 2021 15:50:00
User entered 'No (N)'	System	24 Mar 2021 15:50:00

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

Have you been exposed to someone with 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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-03-24T11:49:53-04:00', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '8cab3d70-3e36-4127-a600-81d14b6e61cd'	System	24 Mar 2021 15:50:00
User entered 'No (N)'	System	24 Mar 2021 15:50:00

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-03-24T11:49:56-04:00', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '8cab3d70-3e36-4127-a600-81d14b6e61cd' User entered '24 Mar 2021 11:49:56'	System	24 Mar 2021 15:50:00
	System	24 Mar 2021 15:50:00

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 11:41:53



**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 11:41:53

US3832055

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-03-31T07:45:48-04:00', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '86afe4e3-8a71-4c18-8113-e4842be6a58a' User entered 'No (N)'	System	31 Mar 2021 11:45:57
	System	31 Mar 2021 11:45:57

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

Have you been exposed to someone with 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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-03-31T07:45:52-04:00', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '86afe4e3-8a71-4c18-8113-e4842be6a58a'	System	31 Mar 2021 11:45:57
User entered 'No (N)'	System	31 Mar 2021 11:45:57

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-03-31T07:45:54-04:00', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '86afe4e3-8a71-4c18-8113-e4842be6a58a' User entered '31 Mar 2021 07:45:54'	System	31 Mar 2021 11:45:57
	System	31 Mar 2021 11:45:57

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-04-07T08:35:29-04:00', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '7fcf75ea-da96-44a2-bfaf-f27699650bb1' User entered 'No (N)'	System	07 Apr 2021 12:35:39



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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

Have you been exposed to someone with 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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-04-07T08:35:33-04:00', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '7fcf75ea-da96-44a2-bfaf-f27699650bb1'	System	07 Apr 2021 12:35:39
User entered 'No (N)'	System	07 Apr 2021 12:35:39

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-04-07T08:35:37-04:00', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '7fcf75ea-da96-44a2-bfaf-f27699650bb1' User entered '07 Apr 2021 08:35:37'	System	07 Apr 2021 12:35:39
	System	07 Apr 2021 12:35:39

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-04-15T09:44:18-04:00', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '22a637e4-84e9-42f9-8d9a-87573b6a6906'	System	15 Apr 2021 13:45:45
User entered 'No (N)'	System	15 Apr 2021 13:45:45

US3832055

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

Have you been exposed to someone with 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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-04-15T09:44:22-04:00', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '22a637e4-84e9-42f9-8d9a-87573b6a6906'	System	15 Apr 2021 13:45:45
User entered 'No (N)'	System	15 Apr 2021 13:45:45

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-04-15T09:44:26-04:00', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '22a637e4-84e9-42f9-8d9a-87573b6a6906'	System	15 Apr 2021 13:45:45
User entered '15 Apr 2021 09:44:26'	System	15 Apr 2021 13:45:45



**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-04-21T05:33:37-04:00', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'cdea4402-c785-4990-96d3-8811580ec481'	System	21 Apr 2021 09:33:51
User entered 'No (N)'	System	21 Apr 2021 09:33:51

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

Have you been exposed to someone with 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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-04-21T05:33:42-04:00', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'cdea4402-c785-4990-96d3-8811580ec481'	System	21 Apr 2021 09:33:51
User entered 'No (N)'	System	21 Apr 2021 09:33:51

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-04-21T05:33:49-04:00', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'cdea4402-c785-4990-96d3-8811580ec481'	System	21 Apr 2021 09:33:51
User entered '21 Apr 2021 05:33:49'	System	21 Apr 2021 09:33:51

US3832055

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 11:41:53



**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-04-29T06:38:59-04:00', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '4692918c-3ef3-40ed-bdb3-1a43e010dfca' User entered 'No (N)'	System	29 Apr 2021 10:39:09
	System	29 Apr 2021 10:39:09

US3832055

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:01:20

Have you been exposed to someone with 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 (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-04-29T06:39:04-04:00', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '4692918c-3ef3-40ed-bdb3-1a43e010dfca' User entered 'No (N)'	System	29 Apr 2021 10:39:09

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-04-29T06:39:07-04:00', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: '4692918c-3ef3-40ed-bdb3-1a43e010dfca' User entered '29 Apr 2021 06:39:07'	System	29 Apr 2021 10:39:09
	System	29 Apr 2021 10:39:09

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 11:41:53



**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 11:41:53



**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 11:41:53



**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 11:41:53



**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 11:41:53

US3832055

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 11:41:53



**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 11:41:53



**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 11:41:53



**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 11:41:53

US3832055

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 11:41:53



**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 11:41:53



**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 11:41:53



**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 11:41:53



**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 11:41:53



**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 11:41:53



**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 11:41:53



**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 11:41:53



**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 11:41:53



**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 11:41:53



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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 11:41:53

US3832055

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 11:41:53



**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 11:41:53

**US3832055**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 11:41:53



**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 11:41:53



**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 11:41:53



**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 11:41:53



**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 11:41:53



**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 11:41:53



**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 11:41:53



**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 11:41:53



**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 11:41:53

US3832055

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 11:41:53



**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 11:41:53



**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 11:41:53

**US3832055**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:01:20**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:41:53
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 11:41:53

US3832055

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:01:20

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:11:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-03-04T11:38:58-05:00', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'f4cb15d2-a0ec-4334-9cc8-a97b6c823f4b'	System	04 Mar 2021 16:39:05
User entered 'No (N)'	System	04 Mar 2021 16:39:05



**US3832055**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 10:01:20**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:11:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6102EB8B-57DC-4FC4-8BF7-6BB052A9382A)', Time: '2021-03-04T11:39:02-05:00', User OID: 'PatientReportedOutcome (US3832055)', ODM File OID: 'f4cb15d2-a0ec-4334-9cc8-a97b6c823f4b' User entered '04 Mar 2021 11:39:02'	System	04 Mar 2021 16:39:05
	System	04 Mar 2021 16:39:05

US3832055

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	04 Nov 2020 15:04:36

US3832055

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '4 Nov 2020'	Alyssa-Kay Peay (b) (4)	04 Nov 2020 15:04:36

US3832055

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4)	04 Nov 2020 15:04:36

US3832055

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered empty.	Alyssa-Kay Peay (b) (4)	04 Nov 2020 15:04:36

US3832055

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:01:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	04 Nov 2020 15:04:42

US3832055

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:01:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:15:16
User entered 'I'	System	04 Nov 2020 15:04:42

US3832055

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:29:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	09 Dec 2020 17:15:37



US3832055

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:29:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '9 Dec 2020'	Alyssa-Kay Peay (b) (4)	09 Dec 2020 17:15:37

US3832055

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:29:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4)	09 Dec 2020 17:15:37

US3832055

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:29:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered empty.	Alyssa-Kay Peay (b) (4)	09 Dec 2020 17:15:37

US3832055

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:01:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:29:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	09 Dec 2020 17:15:41

US3832055

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:01:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:29:57
User entered 'I'	System	09 Dec 2020 17:15:41

US3832055

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:29:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'Yes (Y)'	Emma Partin (b) (4)	30 Dec 2020 15:09:49

US3832055

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:29:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 07:07:25
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'Will be noted as a PD' (Site from System).	Danyel Johnson (b) (4) (b) (4)	26 Jan 2021 20:13:22
User entered '25 Dec 2020' reason for change: Data Entry Error	Emma Partin (b) (4) (b) (4)	30 Dec 2020 15:11:10
User entered '29 Dec 2020' reason for change: Data Entry Error	Emma Partin (b) (4) (b) (4)	30 Dec 2020 15:10:43
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	30 Dec 2020 15:09:49
User entered '30 Dec 2020'	Emma Partin (b) (4) (b) (4)	30 Dec 2020 15:09:49

US3832055

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:29:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'Contact Made (CONTACT MADE)'	Emma Partin (b) (4)	30 Dec 2020 15:09:49



US3832055

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:29:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered empty.	Emma Partin (b) (4)	30 Dec 2020 15:09:49

US3832055

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:01:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:29:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'Yes (Y)'	Emma Partin (b) (4)	30 Dec 2020 15:12:46

US3832055

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:01:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:29:57
User entered 'I'	System	30 Dec 2020 15:12:46

US3832055

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:30:03
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	03 Feb 2021 15:25:21

US3832055

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:30:03
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '3 Feb 2021'	Rodolfo Barrera (b) (4)	03 Feb 2021 15:25:21

US3832055

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:30:03
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'Contact Made (CONTACT MADE)'	Rodolfo Barrera (b) (4)	03 Feb 2021 15:25:21

US3832055

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:30:03
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered empty.	Rodolfo Barrera (b) (4)	03 Feb 2021 15:25:21

US3832055

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:01:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:30:03
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	03 Feb 2021 15:25:27



US3832055

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:01:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 16:30:03
User entered 'I'	System	03 Feb 2021 15:25:27

US3832055

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:01:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:02:12
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	22 Mar 2021 14:48:45

US3832055

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:01:20

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:02:12
User entered '22 Mar 2021'	Danyel Johnson (b) (4)	22 Mar 2021 14:48:45

US3832055

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:01:20

[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 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:02:12
User entered 'Clinic (Clinic)'	Danyel Johnson (b) (4)	22 Mar 2021 14:48:45

US3832055

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:01:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered 'VISIT4'	System	22 Mar 2021 14:48:45

US3832055

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:02:12
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	30 Mar 2021 17:54:10

US3832055

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:02:12
User entered empty.	Alyssa-Kay Peay (b) (4)	30 Mar 2021 17:54:10

US3832055

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:02:12
User entered empty.	Alyssa-Kay Peay (b) (4)	30 Mar 2021 17:54:10



US3832055

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered empty.	System	30 Mar 2021 17:54:10

US3832055

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:02:12
User entered empty.	Alyssa-Kay Peay (b) (4)	30 Mar 2021 17:54:10

US3832055

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:02:12
User entered empty.	Alyssa-Kay Peay (b) (4)	30 Mar 2021 17:54:10

US3832055

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:02:12
User entered empty.	Alyssa-Kay Peay (b) (4)	30 Mar 2021 17:54:10

US3832055

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:02:12
User entered empty.	Alyssa-Kay Peay (b) (4)	30 Mar 2021 17:54:10

US3832055

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered empty.	System	30 Mar 2021 17:54:10

US3832055

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:02:12
User entered empty.	Alyssa-Kay Peay (b) (4)	30 Mar 2021 17:54:10

US3832055

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered empty.	System	30 Mar 2021 17:54:10



US3832055

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:02:12
User entered empty.	Alyssa-Kay Peay (b) (4)	30 Mar 2021 17:54:10

US3832055

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered empty.	System	30 Mar 2021 17:54:10

US3832055

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:02:12
User entered empty.	Alyssa-Kay Peay (b) (4)	30 Mar 2021 17:54:10

US3832055

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered empty.	System	30 Mar 2021 17:54:10

US3832055

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42

US3832055

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:01:20

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42

US3832055

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:01:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:02:12
User entered 'No (N)'	Danyel Johnson (b) (4)	22 Mar 2021 14:48:51

US3832055

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:01:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:02:12
User entered empty.	Danyel Johnson (b) (4)	22 Mar 2021 14:48:51



US3832055

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:01:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:02:12
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	22 Mar 2021 14:49:04

US3832055

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:01:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:02:12
User entered '22 Mar 2021'	Danyel Johnson (b) (4)	22 Mar 2021 14:49:04

US3832055

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:01:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:02:12
User entered '09:10'	Danyel Johnson (b) (4)	22 Mar 2021 14:49:04

US3832055

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:01:20

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered '22 Mar 2021 09:10'	System	22 Mar 2021 14:49:04

US3832055

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:01:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:02:12
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	22 Mar 2021 14:49:09

US3832055

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:01:20

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:33:42
User entered 'I'	System	22 Mar 2021 14:49:09

US3832055

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:02:12
	(b) (4)	
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	05 Apr 2021 15:11:43
	(b) (4)	

US3832055

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:02:12
	(b) (4)	
User entered '5 Apr 2021'	Rodolfo Barrera (b) (4)	05 Apr 2021 15:11:43
	(b) (4)	



US3832055

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:02:12
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Rodolfo Barrera (b) (4)	05 Apr 2021 15:11:43
	(b) (4)	

US3832055

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:01:20

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:02:12
	(b) (4)	
User entered empty.	Rodolfo Barrera (b) (4)	05 Apr 2021 15:11:43
	(b) (4)	

US3832055

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:01:20

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:02:12
	(b) (4)	
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	05 Apr 2021 15:11:49
	(b) (4)	

**US3832055**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:01:20**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 15:11:49

US3832055

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:01:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:43:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'Yes (Y)'	Emma Partin (b) (4)	06 Jan 2021 21:05:00

US3832055

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:01:20

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:43:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '4 Jan 2021'	Emma Partin (b) (4)	06 Jan 2021 21:05:00

US3832055

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:01:20

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:43:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'Clinic (Clinic)'	Emma Partin (b) (4)	06 Jan 2021 21:05:00

US3832055

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:01:20

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:43:28
User entered 'UNBLND_DECIDE'	System	06 Jan 2021 21:05:00



US3832055

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:01:20

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:43:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '4 Jan 2021'	Emma Partin (b) (4)	06 Jan 2021 21:05:28

US3832055

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:01:20

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:43:28
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:02:12
User entered '0'	Rodolfo Barrera (b) (4)	08 Apr 2021 19:58:49
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:12:48

US3832055

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:01:20

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:43:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'Yes (Y)'	Emma Partin (b) (4)	06 Jan 2021 21:05:28

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:01:20

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:43:28
User closed query 'Per CDM, per Sponsor Review: IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 01:48:37
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:02:12
Query 'Per CDM, per Sponsor Review: IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'Updated.' (Site from DM).	Rodolfo Barrera (b) (4)	08 Apr 2021 19:58:56
User entered 'Amendment 6 or later (Amendment 6 or later)'	Rodolfo Barrera (b) (4)	08 Apr 2021 19:58:49
User opened query 'Per CDM, per Sponsor Review: IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 15:46:20
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:12:48

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:01:20

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:43:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '4 Jan 2021'	Emma Partin (b) (4)	06 Jan 2021 21:05:28

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:01:20

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:43:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'mRNA-1273 (mRNA-1273)'	Emma Partin (b) (4)	06 Jan 2021 21:05:28

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:01:20

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:43:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 06:02:19
User entered 'mRNA-1273 (mRNA-1273)'	Emma Partin (b) (4)	06 Jan 2021 21:05:28
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:01:20

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:43:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 06:02:19
User entered 'mRNA-1273 (mRNA-1273)'	Emma Partin (b) (4)	06 Jan 2021 21:05:28
	(b) (4)	



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:01:20

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:43:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'No (N)'	Emma Partin (b) (4)	06 Jan 2021 21:05:28

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:01:20

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:43:28
User entered empty.	System	06 Jan 2021 21:05:28

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**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 10:01:20**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:43:28
User entered empty.	System	06 Jan 2021 21:05:28

US3832055

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:01:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:43:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'Yes (Y)'	Emma Partin (b) (4)	06 Jan 2021 21:05:41

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:01:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:43:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '4 Jan 2021'	Emma Partin (b) (4)	06 Jan 2021 21:05:41

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:01:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:43:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '13:00'	Emma Partin (b) (4)	06 Jan 2021 21:05:41

US3832055

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:01:20

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:43:28
User entered '4 Jan 2021 13:00'	System	06 Jan 2021 21:05:41

US3832055

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:01:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:43:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'Yes (Y)'	Emma Partin (b) (4)	06 Jan 2021 21:05:50



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:01:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:43:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '4 Jan 2021'	Emma Partin (b) (4)	06 Jan 2021 21:05:50

US3832055

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:01:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:43:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '13:00'	Emma Partin (b) (4)	06 Jan 2021 21:05:50

US3832055

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 10:01:20**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:43:28
User entered '4 Jan 2021 13:00'	System	06 Jan 2021 21:05:50

US3832055

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:01:20

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:42
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:50:13
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	23 Sep 2020 21:01:10

US3832055

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:01:20

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:56:51
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:46:09
User entered	System	24 Sep 2020 01:46:04
'USA-US100-2020-mRNA-1273-P301000004'		
User entered 'New'	(b) (4), (b) (6)	24 Sep 2020 01:46:04

US3832055

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:01:20

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:56:52
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Disturbances in consciousness NEC, PT: Syncope, LLT: Syncopal attack - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 21:13:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 21:13:37
Data point term sent to Coder	System	23 Sep 2020 21:13:17
User entered 'Syncopal episode'	Alyssa-Kay Peay (b) (4)	23 Sep 2020 21:12:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:01:20

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:56:54
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	23 Sep 2020 21:12:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:01:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:57:21
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	23 Sep 2020 21:12:19



US3832055

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:01:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:00:58
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	23 Sep 2020 21:12:19

US3832055

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:01:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:00:59
User entered '20 Sep 2020'	Alyssa-Kay Peay (b) (4)	23 Sep 2020 21:12:19
	(b) (4)	

US3832055

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:01:20

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:01:01
User entered empty.	Alyssa-Kay Peay (b) (4)	23 Sep 2020 21:12:19
	(b) (4)	

**US3832055**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:01:20**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 21:12:19

US3832055

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:01:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:01:04
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	23 Sep 2020 21:12:19
	(b) (4)	

US3832055

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:01:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR - RQ: Site's response noted. However, end date of the event is not equal to Hospital discharge. The event may already been resolved but the patient is still admitted. Review and update AE eCRF. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 01:37:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
Query 'Per DM CLR - RQ: Site's response noted. However, end date of the event is not equal to Hospital discharge. The event may already been resolved but the patient is still admitted. Review and update AE eCRF. Otherwise, clarify.' answered with 'The date of resolve matches the date of discharge' (Site from DM).	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 16:15:25
User opened query 'Per DM CLR - RQ: Site's response noted. However, end date of the event is not equal to Hospital discharge. The event may already been resolved but the patient is still admitted. Review and update AE eCRF. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 03:24:01
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:01:21
User closed query 'Per DM CLR: Please review and confirm the stop date of this condition as this is unexpected since this is only episodic and not continuous for more than 1 day. Review and verify the duration of this AE and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 15:00:31
Query 'Per DM CLR: Please review and confirm the stop date of this condition as this is unexpected since this is only episodic and not continuous for more than 1 day. Review and verify the duration of this AE and update as appropriate. Otherwise, provide clarification.' answered with 'Although syncopal episode was a single event, site documented it as a continuous event due to it being the primary dx for hospital admission. ' (Site from DM).	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:55:15

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review and confirm the stop date of this condition as this is unexpected since this is only episodic and not continuous for more than 1 day. Review and verify the duration of this AE and update as appropriate. Otherwise, provide clarification.' (Site from DM). User entered '23 Sep 2020'	(b) (4), (b) (6)	01 Oct 2020 09:51:26
	Alyssa-Kay Peay (b) (4)	23 Sep 2020 21:12:19
	(b) (4)	

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End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:01:26
User entered empty.	Alyssa-Kay Peay (b) (4)	23 Sep 2020 21:12:19
	(b) (4)	



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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 21:12:19

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:01:24
User entered 'Grade 3/Severe (Grade 3/Severe)'	Alyssa-Kay Peay (b) (4)	23 Sep 2020 21:12:19
	(b) (4)	

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:01:28
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	23 Sep 2020 21:12:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:01:20

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:01:30
User entered '0'	Alyssa-Kay Peay (b) (4)	23 Sep 2020 21:12:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:01:32
User entered '0'	Alyssa-Kay Peay (b) (4)	23 Sep 2020 21:12:19
	(b) (4)	

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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.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:01:34
User entered 'I'	Alyssa-Kay Peay (b) (4)	23 Sep 2020 21:12:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:01:36
User entered '20 Sep 2020'	Alyssa-Kay Peay (b) (4)	23 Sep 2020 21:12:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:01:20

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:01:37
User entered '23 Sep 2020'	Alyssa-Kay Peay (b) (4)	23 Sep 2020 21:12:19
	(b) (4)	



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Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:01:39
User closed query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	23 Sep 2020 21:12:48
Query 'Admitted to ICU?' is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		23 Sep 2020 21:12:48
User entered 'No (N)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	23 Sep 2020 21:12:48
User opened query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	23 Sep 2020 21:12:19
User entered 'Unknown (UNK)'	Alyssa-Kay Peay (b) (4) (b) (4)	23 Sep 2020 21:12:19

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:01:41
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	23 Sep 2020 21:12:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:01:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:01:43
User entered '0'	Alyssa-Kay Peay (b) (4)	23 Sep 2020 21:12:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:01:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:01:45
User entered '0'	Alyssa-Kay Peay (b) (4)	23 Sep 2020 21:12:19
	(b) (4)	

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Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:01:46
User entered '0'	Alyssa-Kay Peay (b) (4)	23 Sep 2020 21:12:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:01:48
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 18:08:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Sep 2020 18:08:49
User entered 'Not Related (NOT RELATED)' reason for change: New Information	Alyssa-Kay Peay (b) (4) (b) (4)	24 Sep 2020 18:08:49
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 21:12:19
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	23 Sep 2020 21:12:19

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:01:50
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Sep 2020 18:08:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Sep 2020 18:08:49
User entered 'Not Related (NOT RELATED)' reason for change: New Information	Alyssa-Kay Peay (b) (4) (b) (4)	24 Sep 2020 18:08:49
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Sep 2020 21:12:19
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	23 Sep 2020 21:12:19

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Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:01:51
User entered 'Not Applicable (NOT APPLICABLE)'	Alyssa-Kay Peay (b) (4) (b) (4)	23 Sep 2020 21:12:19



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Form: Adverse Events (1)

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None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:23:36
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '0' reason for change: Data Entry Error	(b) (4)	09 Feb 2021 16:19:04
DataPoint Un-verified.	Danyel Johnson (b) (4)	03 Dec 2020 16:07:13
User entered '1' reason for change: Data Entry Error	(b) (4)	03 Dec 2020 16:07:13
DataPoint Verified.	Danyel Johnson (b) (4)	23 Nov 2020 18:01:46
User closed query 'Per DM CLR: Serious= YES. However, no Other action taken was noted (no CM/CP). Per SAE Narrative unknown diagnostic procedures were performed. Please review and ensure that diagnostic procedures (even UNKNOWN) were recorded in the CP eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 15:19:24
Query 'Per DM CLR: Serious= YES. However, no Other action taken was noted (no CM/CP). Per SAE Narrative unknown diagnostic procedures were performed. Please review and ensure that diagnostic procedures (even UNKNOWN) were recorded in the CP eCRF as appropriate.' answered with 'Data updated' (Site from DM).	Danyel Johnson (b) (4)	11 Nov 2020 14:53:29
User entered '0' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 14:53:17
User opened query 'Per DM CLR: Serious= YES. However, no Other action taken was noted (no CM/CP). Per SAE Narrative unknown diagnostic procedures were performed. Please review and ensure that diagnostic procedures (even UNKNOWN) were recorded in the CP eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 09:51:39
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	23 Sep 2020 21:16:16
User entered '1' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	23 Sep 2020 21:16:16
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	23 Sep 2020 21:12:19

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None

Audit	User	Time (GMT)
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	23 Sep 2020 21:12:19

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, the corresponding ConMed of Lisinopril is not the usual treatment for this AE and was given after the End date of this AE. Please review and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 10:09:52
Query 'Per DM CLR: Other Action Taken = ConMed. However, the corresponding ConMed of Lisinopril is not the usual treatment for this AE and was given after the End date of this AE. Please review and update applicable details as appropriate. Otherwise, clarify.' answered with 'Correct as reported per review of medical records' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	15 Mar 2021 15:26:44
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, the corresponding ConMed of Lisinopril is not the usual treatment for this AE and was given after the End date of this AE. Please review and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 18:35:51
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 15:34:23
User closed query 'per CM list, lisinopril was given for syncopal episode. Please confirm and update.' (Site from CRA).	(b) (4), (b) (6)	10 Feb 2021 15:34:21
Query 'per CM list, lisinopril was given for syncopal episode. Please confirm and update.' answered with 'Reviewed and updated' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 16:19:22
User entered '1' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 16:19:04
User opened query 'per CM list, lisinopril was given for syncopal episode. Please confirm and update.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 18:29:43
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please update to record the corresponding ConMed treatment for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 10:07:53

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please update to record the corresponding ConMed treatment for this AE as appropriate. Otherwise, clarify.' answered with 'Removed as no medication was given to treat Syncopal Episode ' (Site from DM). DataPoint Un-verified.	Danyel Johnson (b) (4)	03 Dec 2020 16:07:48
	(b) (4)	
	Danyel Johnson (b) (4)	03 Dec 2020 16:07:13
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Danyel Johnson (b) (4)	03 Dec 2020 16:07:13
	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please update to record the corresponding ConMed treatment for this AE as appropriate. Otherwise, clarify.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 02:20:29
	(b) (4), (b) (6)	23 Nov 2020 18:01:48
DataPoint Un-verified.	Danyel Johnson (b) (4)	11 Nov 2020 14:53:17
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Danyel Johnson (b) (4)	11 Nov 2020 14:53:17
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:04:20
User entered '0'	Alyssa-Kay Peay (b) (4)	23 Sep 2020 21:12:19
	(b) (4)	

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:23:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:34:18
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 15:34:14
User closed query 'Per DM CLR: Other Action Taken = Concomitant Procedure. However, there is not recorded therapeutic procedure that match this AE within this time frame. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 10:14:52
Query 'Per DM CLR: Other Action Taken = Concomitant Procedure. However, there is not recorded therapeutic procedure that match this AE within this time frame. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' answered with 'Removed as no procedure was Completed to treat Syncopal Episode' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	03 Dec 2020 16:07:46
DataPoint Un-verified.	Danyel Johnson (b) (4) (b) (4)	03 Dec 2020 16:07:13
User entered '0' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	03 Dec 2020 16:07:13
User opened query 'Per DM CLR: Other Action Taken = Concomitant Procedure. However, there is not recorded therapeutic procedure that match this AE within this time frame. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 02:20:38
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:01:50
DataPoint Un-verified.	Danyel Johnson (b) (4) (b) (4)	11 Nov 2020 14:53:17
User entered '1' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	11 Nov 2020 14:53:17
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:04:21
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	23 Sep 2020 21:12:19

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:04:23
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Alyssa-Kay Peay (b) (4)	23 Sep 2020 21:12:19
	(b) (4)	

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:04:31
User entered empty.	Alyssa-Kay Peay (b) (4)	23 Sep 2020 21:12:19
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative indicates that the subject underwent CT of Head and Spine. However, there is no recorded Concomitant Procedure that match the information. Please update to record the corresponding procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 10:10:20
User closed query 'Per DM CLR: Narrative indicates that the subject had fractures of Anterior/Posterior Maxillary Walls, Nondisplaced Zygomatic Arch and Right Periorbital Soft Tissue Swelling and Hematoma. However, there are no recorded AEs that match these conditions. Please review and update to record the corresponding AEs as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 15:31:27
Query 'Per DM CLR: Narrative indicates that the subject underwent CT of Head and Spine. However, there is no recorded Concomitant Procedure that match the information. Please update to record the corresponding procedure as appropriate. Otherwise, clarify.' answered with 'Please see log line 7' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	15 Mar 2021 15:39:37
Query 'Per DM CLR: Narrative indicates that the subject had fractures of Anterior/Posterior Maxillary Walls, Nondisplaced Zygomatic Arch and Right Periorbital Soft Tissue Swelling and Hematoma. However, there are no recorded AEs that match these conditions. Please review and update to record the corresponding AEs as appropriate. Otherwise, clarify.' answered with 'Please see log line 2' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	15 Mar 2021 15:37:15
User opened query 'Per DM CLR: Narrative indicates that the subject underwent CT of Head and Spine. However, there is no recorded Concomitant Procedure that match the information. Please update to record the corresponding procedure as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 18:37:07



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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative indicates that the subject had fractures of Anterior/Posterior Maxillary Walls, Nondisplaced Zygomatic Arch and Right Periorbital Soft Tissue Swelling and Hematoma. However, there are no recorded AEs that match these conditions. Please review and update to record the corresponding AEs as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 18:36:22
User closed query ' PER CDM RQ: Kindly note that all events should be recorded separately as applicable. Any injuries sustained due to syncopal episode should be recorded separately on applicable eCRF. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 21:00:10
User closed query 'Response noted, however no record of CT OF HEAD AND SPINE in procedures. Kindly review and update. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 21:00:09
User closed query ' Per DM CLR: SAE Narrative = OXYCODONE-ACETAMINOPHEN 7.5-325MG Q 4-6 HRS PRN. However, please ensure that the dose is consistent with the CM eCRF. Please review and reconcile data as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 21:00:07
User closed query 'Per DM CLR: SAE Narrative = SUBJECT WAS SWITCHED FROM NORVASC TO LISINOPRIL. However, this AMLODIPINE is still ongoing in the CM eCRF. Please review and reconcile data as appropriate.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 21:00:06
Query ' PER CDM RQ: Kindly note that all events should be recorded separately as applicable. Any injuries sustained due to syncopal episode should be recorded separately on applicable eCRF. ' answered with 'Reviewed and updated ' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	23 Feb 2021 20:42:39
Query 'Response noted, however no record of CT OF HEAD AND SPINE in procedures. Kindly review and update. ' answered with 'Reviewed and updated ' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	23 Feb 2021 20:40:52
User opened query ' PER CDM RQ: Kindly note that all events should be recorded separately as applicable. Any injuries sustained due to syncopal episode should be recorded separately on applicable eCRF. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 01:43:37

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PER CDM RQ: Kindly note that all events should be recorded separately as applicable. ' canceled (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 01:42:33
Query 'PER CDM RQ: Kindly note that all events should be recorded separately as applicable' canceled (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 01:42:02
User closed query 'Per DM CLR: SAE Narrative = HYPONATREMIA CHLORIDE LEVELS. However, this is not recorded in the ConProc eCRF (i.e., Blood work-up). Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 01:41:55
User closed query 'Per DM CLR: SAE Narrative = EKG COMPLETED. 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)	23 Feb 2021 01:41:24
User opened query 'PER CDM RQ: Kindly note that all events should be recorded separately as applicable (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 01:41:05
User closed query 'Per DM CLR: SAE Narrative = NONDISPLACED ZYGOMATIC ARCH FRACTURE. However, please review and verify if this 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)	23 Feb 2021 01:41:05
User opened query 'PER CDM RQ: Kindly note that all events should be recorded separately as applicable. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 01:40:48
User closed query 'Per DM CLR: SAE Narrative = PRESENTED TO THE ER ON 9/20/2020 AFTER A SYNCOPE EPISODE AND FALL. However, please review and verify if 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)	23 Feb 2021 01:40:48
User opened query 'Response noted, however no record of CT OF HEAD AND SPINE in procedures. Kindly review and update. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 01:39:01

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE Narrative = CT OF THE HEAD AND SPINE COMPLETED. 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)	23 Feb 2021 01:39:01
User closed query 'Per DM CLR: SAE Narrative = CT OF THE FACIAL BONES WAS COMPLETED. 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)	23 Feb 2021 01:38:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
Query 'Per DM CLR: SAE Narrative = OXYCODONE-ACETAMINOPHEN 7.5-325MG Q 4-6 HRS PRN. However, please ensure that the dose is consistent with the CM eCRF. Please review and reconcile data as appropriate.	(b) (4)	
' answered with 'Updated' (Site from DM).	Danyel Johnson (b) (4)	09 Feb 2021 16:30:00
Query 'Per DM CLR: SAE Narrative = SUBJECT WAS SWITCHED FROM NORVASC TO LISINOPRIL. However, this AMLODIPINE is still ongoing in the CM eCRF. Please review and reconcile data as appropriate.'	(b) (4)	
' answered with 'Updated' (Site from DM).	Danyel Johnson (b) (4)	09 Feb 2021 16:29:43
Query 'Per DM CLR: SAE Narrative = HYPONATREMIA CHLORIDE LEVELS. However, this is not recorded in the ConProc eCRF (i.e., Blood work-up). Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Updated' (Site from DM).	Danyel Johnson (b) (4)	09 Feb 2021 16:29:26
Query 'Per DM CLR: SAE Narrative = EKG COMPLETED. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Updated' (Site from DM).	Danyel Johnson (b) (4)	09 Feb 2021 16:29:08

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE Narrative = NONDISPLACED ZYGOMATIC ARCH FRACTURE. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'This was a symptom secondary to the Syncope episode please clarify if this should be noted as an AE' (Site from DM).	Danyel Johnson (b) (4)	09 Feb 2021 16:23:20
Query 'Per DM CLR: SAE Narrative = CT OF THE HEAD AND SPINE COMPLETED. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Updated' (Site from DM).	Danyel Johnson (b) (4)	09 Feb 2021 16:22:21
Query 'Per DM CLR: SAE Narrative = CT OF THE FACIAL BONES WAS COMPLETED. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'reviewed and updated ' (Site from DM).	Danyel Johnson (b) (4)	09 Feb 2021 16:20:48
Query 'Per DM CLR: SAE Narrative = PRESENTED TO THE ER ON 9/20/2020 AFTER A SYNCOPE EPISODE AND FALL. However, please review and verify if FALL should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'The fall was caused by the syncope episode would this not be considered a the symptom of the syncope episode?' (Site from DM).	Danyel Johnson (b) (4)	09 Feb 2021 16:19:30
User opened query ' Per DM CLR: SAE Narrative = OXYCODONE-ACETAMINOPHEN 7.5-325MG Q 4-6 HRS PRN. However, please ensure that the dose is consistent with the CM eCRF. Please review and reconcile data as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 03:25:39
User opened query 'Per DM CLR: SAE Narrative = SUBJECT WAS SWITCHED FROM NORVASC TO LISINAPRIL. However, this AMLODIPINE is still ongoing in the CM eCRF. Please review and reconcile data as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 03:25:30

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = HYPONATREMIA CHLORIDE LEVELS. However, this is not recorded in the ConProc eCRF (i.e., Blood work-up). Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 03:25:24
User opened query 'Per DM CLR: SAE Narrative = EKG COMPLETED. 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)	18 Jan 2021 03:25:18
User opened query 'Per DM CLR: SAE Narrative = NONDISPLACED ZYGOMATIC ARCH FRACTURE. However, please review and verify if this 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)	18 Jan 2021 03:25:13
User opened query 'Per DM CLR: SAE Narrative = CT OF THE HEAD AND SPINE COMPLETED. 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)	18 Jan 2021 03:25:06
User opened query 'Per DM CLR: SAE Narrative = CT OF THE FACIAL BONES WAS COMPLETED. 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)	18 Jan 2021 03:25:00
User opened query 'Per DM CLR: SAE Narrative = PRESENTED TO THE ER ON 9/20/2020 AFTER A SYNCOPE EPISODE AND FALL. However, please review and verify if 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)	18 Jan 2021 03:24:55
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:02:08
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)	12 Nov 2020 15:16:03

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EAB) (1725)

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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 report any pre or post syncopal symptoms, duration that subject was unconscious and clinical course.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 15:16:00
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)	12 Nov 2020 15:15:52
User closed query 'PV Query: Please provide the etiology of the syncope and consider updating the event term if appropriate.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 15:15:45
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 confirm so.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 15:15:32
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results, once medical records received. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 15:15:28
Query 'PV Query: Please provide the etiology of the syncope and consider updating the event term if appropriate.' answered with 'No cause has been noted per review of medical records ' (Site from Safety).	Danyel Johnson (b) (4)	11 Nov 2020 14:55:09
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Sent per request' (Site from Safety).	Danyel Johnson (b) (4)	11 Nov 2020 14:54:38
Query 'PV Query: Please report any pre or post syncopal symptoms, duration that subject was unconscious and clinical course.' answered with 'Non reported per subject and per review of medical records' (Site from Safety).	Danyel Johnson (b) (4)	11 Nov 2020 14:54:27

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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 'No Covid testing completed per review of records' (Site from Safety).	Danyel Johnson (b) (4)	11 Nov 2020 14:54:04
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 confirm so.' answered with 'Data updated' (Site from Safety).	Danyel Johnson (b) (4)	11 Nov 2020 14:53:43
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results, once medical records received. Please include units and reference ranges if applicable.' answered with 'Data updated ' (Site from Safety).	Danyel Johnson (b) (4)	11 Nov 2020 14:53:36

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[Narrative](#)

Audit	User	Time (GMT)
User entered '71 y/o randomized male who received the first dose of blinded mRNA-1273 or placebo for SARS-CoV-2 vaccination on 8/3/2020 and his second, final dose of study drug, on 09/09 2020. Presented to the ER on 9/20/2020 after a syncope episode and fall. A CT of the facial bones was completed with the following findings fracture of the medial and lateral right orbital wall the orbital floor and the anterior/posterior maxillary sinus walls. Nondisplaced zygomatic arch fracture and Right periorbital soft tissue swelling and hematoma. A CT of the head and spine completed noted within normal limits. EKG completed noted WNL. Admission diagnoses include: Syncope and collapse, closed fracture of lateral wall of the right orbit and  hyponatremia chloride levels:  9/22/2020: 91 mmol/l  9/21/2020: 91mmol/l  9/20/2020: 90mmol/L  reference range 98-107mmol/L Subject was scheduled for open reduction, internal fixation of the right zygomaticomaxillary complex fracture.  Subject was switched from Norvasc to lisinopril and told to continue Bystolic  Discharged 09/23/2020 New medications Lisinopril 5mg 9/24/2020 1 po qd Sodium chloride 1g tablet po tid Oxycodone-Acetaminophen 7.5-325mg Q 4-6 hrs prn' reason for change: Data Entry Error DataPoint Un-verified.	Danyel Johnson (b) (4) (b) (4)	11 Nov 2020 14:52:45
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:04:51
User closed query 'Per DM CLR: SAE Narrative = Patient had facial fractures as a result of this AE. However, this information was not recorded in the AE eCRF. Please review and ensure that this is recorded as a separate entry in the AE eCRF.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 20:04:37
	(b) (4), (b) (6)	07 Oct 2020 09:07:33



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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 16:51:13
User opened query 'PV Query: Please report any pre or post syncopal symptoms, duration that subject was unconscious and clinical course.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 16:51:05
User opened query 'PV Query: Please provide the etiology of the syncope and consider updating the event term if appropriate.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 16:50:57
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)	02 Oct 2020 16:50:36
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 confirm so.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 16:50:06
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results, once medical records received. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 16:49:55
Query 'Per DM CLR: SAE Narrative = Patient had facial fractures as a result of this AE. However, this information was not recorded in the AE eCRF. Please review and ensure that this is recorded as a separate entry in the AE eCRF.' answered with 'AE of facial fractures updated accordingly.' (Site from DM).	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:38:16
User opened query 'Per DM CLR: SAE Narrative = Patient had facial fractures as a result of this AE. However, this information was not recorded in the AE eCRF. Please review and ensure that this is recorded as a separate entry in the AE eCRF.' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 09:51:58

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Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject was contacted for day 43 safety follow up call. At the time of the call, subject reported being hospitalized from 20 SEP 2020 through 23 SEP 2020. Subject reported facial fracture as a result of the syncopal episode. Subject was not sure of the names of diagnostic tests performed during the course of his hospitalization. Subject reports that no medications were given during hospitalization or at discharge. Subject asked to come by site at his earliest convenience to fill out medical records release form and verbalized understanding. Sit to update upon receipt and review of medical records. Subject instructed to keep follow up appointments that were scheduled at time of discharge and verbalized understanding.'	Alyssa-Kay Peay (b) (4)	23 Sep 2020 21:12:19

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Folder: Adverse Events

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	23 Sep 2020 21:12:19

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**Folder:** Adverse Events

**Form:** Adverse Events (1)

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Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	23 Sep 2020 21:12:19

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Sep 2020 21:12:19

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Folder: Adverse Events

Form: Adverse Events (2)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:34

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:01:20

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Skull fractures, facial bone fractures and dislocations, PT: Facial bones fracture, LLT: Orbital fracture - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 03:19:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 03:19:39
Data point term sent to Coder	System	11 Nov 2020 16:07:47
Coding entries removed.	Danyel Johnson (b) (4)	11 Nov 2020 16:06:53
User entered 'Closed fracture of lateral wall of the right orbit' reason for change: Data Entry Error	Danyel Johnson (b) (4)	11 Nov 2020 16:06:53
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Skull fractures, facial bone fractures and dislocations, PT: Facial bones fracture, LLT: Facial bones fracture - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 16:25:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 16:25:54
Data point term sent to Coder	System	01 Oct 2020 16:24:52
User entered 'Facial Fracture'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:24:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:01:20

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:24:20



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Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'No (N)'	(b) (4) Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:24:20

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:24:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:01:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '20 Sep 2020'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:24:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:01:20

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered empty.	(b) (4) Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:24:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:01:20

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:34
User entered empty.	System	01 Oct 2020 16:24:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:01:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'No (N)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	11 Nov 2020 16:06:53
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:24:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:01:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '23 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Danyel Johnson (b) (4)	11 Nov 2020 16:06:53
User entered empty.	(b) (4)	
	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:24:20
	(b) (4)	

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End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered empty.	(b) (4) Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:24:20



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:01:20

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:34
User entered empty.	System	01 Oct 2020 16:24:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:01:20

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:24:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:01:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'No (N)'	(b) (4) Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:24:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:01:20

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '0'	(b) (4) Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:24:20

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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)	29 Apr 2021 11:39:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '0'	(b) (4) Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:24:20

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Folder: Adverse Events

Form: Adverse Events (2)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '0'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:24:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:01:20

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered empty.	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:24:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:01:20

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered empty.	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:24:20



US3832055

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:01:20

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered empty.	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:24:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:01:20

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered empty.	(b) (4) Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:24:20

US3832055

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:01:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '0'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:24:20

US3832055

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:01:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '0'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:24:20

US3832055

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:01:20

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '0'	(b) (4) Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:24:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:01:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'Not Related (NOT RELATED)'	(b) (4) Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:24:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:01:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'Not Related (NOT RELATED)'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:24:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:01:20

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:24:20
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:01:20

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Danyel Johnson (b) (4)	11 Nov 2020 16:06:53
User entered '1'	(b) (4)	
	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:24:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:01:20

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Danyel Johnson (b) (4)	11 Nov 2020 16:06:53
User entered '0'	(b) (4)	
	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:24:20
	(b) (4)	

US3832055

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:01:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Danyel Johnson (b) (4)	11 Nov 2020 16:06:53
User entered '0'	(b) (4)	
	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:24:20
	(b) (4)	

US3832055

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:01:20

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Danyel Johnson (b) (4)	11 Nov 2020 16:06:53
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4)	
	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:24:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:01:20

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered empty.	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:24:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:01:20

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered empty.	(b) (4) Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:24:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:01:20

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:34
User entered '0'	System	01 Oct 2020 16:24:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:01:20

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:34
User entered 'I'	System	01 Oct 2020 16:24:20



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:01:20

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:34

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:01:20

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:40

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:01:20

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Electrolyte and fluid balance conditions, HLT: Sodium imbalance, PT: Hyponatraemia, LLT: Hyponatremia - version MedDRA\23.0.	Coder Import (b) (4)	01 Oct 2020 16:35:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	01 Oct 2020 16:35:55
Data point term sent to Coder	System	01 Oct 2020 16:35:08
User entered 'Hyponatremia'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:34:37

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:01:20

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:34:37

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:01:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'No (N)'	(b) (4) Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:34:37

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:01:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:34:37

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:01:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '20 Sep 2020'	(b) (4) Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:34:37

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:01:20

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered empty.	(b) (4) Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:34:37



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:01:20

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:40
User entered empty.	System	01 Oct 2020 16:34:37

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:01:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'No (N)'	(b) (4) Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:34:37

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:01:20

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '23 Sep 2020'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:34:37

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:01:20

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered empty.	(b) (4) Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:34:37

US3832055

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:01:20

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:40
User entered empty.	System	01 Oct 2020 16:34:37

US3832055

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:01:20

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	
	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:34:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:01:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'No (N)'	(b) (4) Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:34:37

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:01:20

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '0'	(b) (4) Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:34:37



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:01:20

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '0'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:34:37

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:01:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '0'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:34:37

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:01:20

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered empty.	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:34:37

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:01:20

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered empty.	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:34:37

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:01:20

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered empty.	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:34:37

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:01:20

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered empty.	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:34:37

US3832055

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:01:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '0'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:34:37

US3832055

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:01:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '0'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:34:37



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:01:20

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '0'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:34:37

US3832055

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:01:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Oct 2020 17:33:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 17:33:41
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	21 Oct 2020 17:33:41
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	01 Oct 2020 16:34:37
User entered empty.	System	01 Oct 2020 16:34:37
	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:34:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:01:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
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	21 Oct 2020 17:33:41
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	21 Oct 2020 17:33:41
User opened query 'Data is required. Please complete.' (Site from System).	Alyssa-Kay Peay (b) (4)	21 Oct 2020 17:33:41
User entered empty.	(b) (4)	
	System	01 Oct 2020 16:34:37
	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:34:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:01:20

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:34:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:01:20

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '0'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:34:37

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:01:20

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'I'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:34:37

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:01:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '0'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:34:37

US3832055

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:01:20

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)'	(b) (4) Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:34:37



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:01:20

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'Subject was hospitalized for a syncopial episode 20-23 SEP 2020. During hospitalization, subject was given a dose of Samsca to correct sodium levels. Subject d/c with Sodium Chloride Rx. Stable at d/c'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:34:37

US3832055

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:01:20

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered empty.	(b) (4) Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:34:37

US3832055

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:01:20

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:40
User entered '0'	System	01 Oct 2020 16:34:37

US3832055

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:01:20

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:40
User entered 'I'	System	01 Oct 2020 16:34:37

US3832055

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:01:20

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:39:40

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 10 Jun 2021 10:01:20**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:42
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:17:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:05:39
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:05:07
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 17:22:43

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:01:20

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:06:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 16:17:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 16:17:13
Data point term sent to Coder	System	06 Aug 2020 17:24:50
User entered 'Oxycodone'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 17:23:56

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:01:20**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:06:39
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 17:23:56
	(b) (4)	



US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:01:20**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:06:39
User entered 'Degenerative Disc Disease'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 17:23:56

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:01:20**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:06:39
User entered '325/7.5'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 17:23:56
	(b) (4)	

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:01:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:06:39
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 17:23:56
	(b) (4)	

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:01:20**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:06:39
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 17:23:56
	(b) (4)	

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:01:20**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:06:39
User entered 'as needed (PRN)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 17:23:56
	(b) (4)	

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:01:20**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:06:39
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 17:23:56
	(b) (4)	

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:01:20**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:06:39
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 17:23:56
	(b) (4)	

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:01:20**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:06:39
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 17:23:56
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:01:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:06:39
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 11:49:46
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 17:23:56
User entered 'un UNK 2016'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 17:23:56
	(b) (4)	

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:01:20**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:06:39
User entered '0'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 17:23:56
	(b) (4)	

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:01:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:06:39
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 17:23:56

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:01:20**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:06:39
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 17:23:56
	(b) (4)	

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:01:20**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:06:39
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 17:23:56
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:01:20**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 17:23:56

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:01:20**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 17:23:56

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:01:20**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 17:23:56



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:01:20

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:07:02
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: THYROID, PRODUCTSYNONYM: NATURE THROID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 09:32:28
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 09:32:28
	(b) (4)	
Data point term sent to Coder	System	06 Aug 2020 17:24:51
User entered 'Nature Throid'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 17:24:39
	(b) (4)	

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:01:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:07:02
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 17:24:39
	(b) (4)	

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:01:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:07:02
User entered 'Hypothyroidism'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 17:24:39
	(b) (4)	

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:01:20**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:07:02
User entered '130'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 17:24:39
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:01:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:07:02
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 17:24:39
	(b) (4)	

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:01:20**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:07:02
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 17:24:39
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:01:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:07:02
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 17:24:39
	(b) (4)	

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:01:20

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:07:02
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 17:24:39
	(b) (4)	



US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:01:20**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:07:02
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 17:24:39
	(b) (4)	

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:01:20**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:07:02
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 17:24:39

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:01:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:07:02
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 11:49:50
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 17:24:39
User entered 'un UNK 2015'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 17:24:39
	(b) (4)	

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:01:20**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:07:02
User entered '0'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 17:24:39
	(b) (4)	

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:01:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:07:02
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 17:24:39
	(b) (4)	

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:01:20**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:07:02
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 17:24:39

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:01:20**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:07:02
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 17:24:39
	(b) (4)	

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:01:20**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 17:24:39



US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:01:20**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 17:24:39

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:01:20**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 17:24:39

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:01:20

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:42:46
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:07:20
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 16:40:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 16:40:00
Data point term sent to Coder	System	01 Oct 2020 16:39:16
Coding entries removed.	Alyssa-Kay Peay (b) (4) (b) (4)	01 Oct 2020 16:39:09
User entered 'AMLoDIPINE' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	01 Oct 2020 16:39:09
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 23:59:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 23:59:00
Data point term sent to Coder	System	06 Aug 2020 17:25:53
User entered 'Amlidipine'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 17:25:20

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:01:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:42:46
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:07:20
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 17:25:20

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:01:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:42:46
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:07:20
User entered 'Hypertension'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 17:25:20

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:01:20

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:42:46
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:07:20
User entered '10'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 17:25:20

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:01:20

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:42:46
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:07:20
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 17:25:20

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:01:20**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:42:46
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:07:20
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 17:25:20



US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:01:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:42:46
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:07:20
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 17:25:20

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:01:20**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:42:46
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:07:20
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 17:25:20

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:01:20

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:42:46
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:07:20
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 17:25:20

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:01:20**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:42:46
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:07:20
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 17:25:20

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:01:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:42:46
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:07:20
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 11:49:54
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 17:25:20
User entered 'un UNK 2018'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 17:25:20

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:01:20**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:42:46
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:07:20
User entered '0'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 17:25:20

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:01:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:42:46
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Un-verified.	Danyel Johnson (b) (4)	09 Feb 2021 16:27:17
User entered 'No (N)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	09 Feb 2021 16:27:17
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:07:20
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 17:25:20

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:01:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:42:46
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Un-verified.	Danyel Johnson (b) (4)	09 Feb 2021 16:27:17
User entered '20 Sep 2020' reason for change: Data Entry Error	Danyel Johnson (b) (4)	09 Feb 2021 16:27:17
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:07:20
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 17:25:20



US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:01:20**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:42:46
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:07:20
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 17:25:20

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:01:20**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:42:46
User entered '1'	System	06 Aug 2020 17:25:20

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:01:20**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:42:46
User entered '1'	System	06 Aug 2020 17:25:20

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:01:20**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:42:46
User entered '804 (804)'	System	06 Aug 2020 17:25:20

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:01:20

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:07:38
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 16:42:54
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 16:42:54
	(b) (4)	
Data point term sent to Coder	System	01 Oct 2020 16:41:18
User entered 'Fluticasone propionate'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:41:14
	(b) (4)	

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:01:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:07:38
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:41:14
	(b) (4)	

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:01:20**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:07:38
User entered 'Allergic Rhinitis'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:41:14
	(b) (4)	

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:01:20**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:07:38
User entered '100'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:41:14
	(b) (4)	



US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:01:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:07:38
User entered 'ug (ug)'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:41:14
	(b) (4)	

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:01:20**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:07:38
User entered empty.	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:41:14
	(b) (4)	

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:01:20**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:07:38
User entered 'as needed (PRN)'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:41:14
	(b) (4)	

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:01:20**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:07:38
User entered empty.	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:41:14
	(b) (4)	

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:01:20**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:07:38
User entered 'Nasal (NASAL)'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:41:14
	(b) (4)	

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:01:20**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:07:38
User entered empty.	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:41:14
	(b) (4)	

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:01:20**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:07:38
User entered 'UN UNK 2000'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:41:14
	(b) (4)	

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:01:20**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:07:38
User entered '0'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:41:14
	(b) (4)	



US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:01:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:07:38
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:41:14
	(b) (4)	

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:01:20**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:07:38
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	01 Oct 2020 16:41:14

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:01:20**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:07:38
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:41:14
	(b) (4)	

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:01:20**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 16:41:14

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:01:20**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 16:41:14

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:01:20**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 16:41:14

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:01:20

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:43:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:08:43
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 Oct 2020 16:43:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 16:43:58
Data point term sent to Coder	System	01 Oct 2020 16:42:19
User entered 'Influenza Vaccine'	Alyssa-Kay Peay (b) (4) (b) (4)	01 Oct 2020 16:42:16

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:01:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:43:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.	(b) (4)	(b) (4), (b) (6)
' (Site from DM).		23 Nov 2020 17:23:10
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.	Danyel Johnson (b) (4)	13 Nov 2020 14:03:27
' answered with 'Updated' (Site from DM).	(b) (4)	
DataPoint Un-verified.	Danyel Johnson (b) (4)	13 Nov 2020 14:03:20
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	13 Nov 2020 14:03:20
	(b) (4)	
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate.	(b) (4), (b) (6)	13 Nov 2020 09:30:49
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:08:43
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:42:16
	(b) (4)	



US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:01:20**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:43:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:08:43
User entered 'Vaccination'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:42:16

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:01:20

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:43:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Un-verified.	Danyel Johnson (b) (4)	13 Nov 2020 14:03:20
User entered '0.5' reason for change: Data Entry Error	Danyel Johnson (b) (4)	13 Nov 2020 14:03:20
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:08:43
User entered '1'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:42:16

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:01:20

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:43:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Un-verified.	Danyel Johnson (b) (4)	13 Nov 2020 14:03:20
User entered 'mL (mL)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	13 Nov 2020 14:03:20
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:08:43
User entered 'Other (OTHER)'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:42:16

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:01:20

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:43:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Un-verified.	Danyel Johnson (b) (4)	13 Nov 2020 14:03:20
User entered empty; reason for change Data Entry Error	Danyel Johnson (b) (4)	13 Nov 2020 14:03:20
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:08:43
User entered 'injection'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:42:16

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:01:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:43:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:08:43
User entered 'once (ONCE)'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:42:16

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:01:20

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:43:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:08:43
User entered empty.	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:42:16

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:01:20**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:43:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:08:43
User entered 'Intramuscular (INTRAMUSCULAR)'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:42:16

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:01:20**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:43:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:08:43
User entered empty.	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:42:16



US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:01:20**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:43:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:08:43
User entered '25 Aug 2020'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:42:16

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:01:20**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:43:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:08:43
User entered '0'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:42:16

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:01:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:43:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:08:43
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:42:16

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:01:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:43:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:08:43
User entered '25 Aug 2020'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:42:16

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:01:20**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:43:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:08:43
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:42:16

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:01:20**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:43:54
User entered empty.	System	01 Oct 2020 16:42:16

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:01:20**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:43:54
User entered empty.	System	01 Oct 2020 16:42:16

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:01:20**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:43:54
User entered empty.	System	01 Oct 2020 16:42:16



US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:01:20

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:09:05
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: NEBIVOLOL HYDROCHLORIDE, PRODUCTSYNONYM: BYSTOLIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 16:43:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 16:43:59
Data point term sent to Coder	System	01 Oct 2020 16:43:21
User entered 'Bystolic'	Alyssa-Kay Peay (b) (4) (b) (4)	01 Oct 2020 16:43:03

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:01:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:09:05
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	01 Oct 2020 16:43:03

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:01:20**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:09:05
User entered 'hypertension'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:43:03
	(b) (4)	

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:01:20**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:09:05
User entered '10'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:43:03
	(b) (4)	

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:01:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:09:05
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	01 Oct 2020 16:43:03

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:01:20**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:09:05
User entered empty.	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:43:03
	(b) (4)	

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:01:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:09:05
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:43:03
	(b) (4)	

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:01:20**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:09:05
User entered empty.	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:43:03
	(b) (4)	



US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:01:20**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:09:05
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:43:03
	(b) (4)	

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:01:20**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:09:05
User entered empty.	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:43:03
	(b) (4)	

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:01:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:09:05
User entered 'UN Jan 2020'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:43:03
	(b) (4)	

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:01:20**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:09:05
User entered '0'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:43:03
	(b) (4)	

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:01:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:09:05
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:43:03
	(b) (4)	

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:01:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:09:05
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	01 Oct 2020 16:43:03

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:01:20**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:09:05
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	01 Oct 2020 16:43:03

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:01:20**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 16:43:03



US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:01:20**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 16:43:03

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:01:20**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 16:43:03

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:01:20

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:17:00
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 22:55:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 22:55:52
Data point term sent to Coder	System	01 Oct 2020 16:44:25
User entered 'Lisinopril'	Alyssa-Kay Peay (b) (4) (b) (4)	01 Oct 2020 16:44:01

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:01:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:17:00
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:44:01
	(b) (4)	

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:01:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected 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) (4), (b) (6)	27 Jan 2021 07:06:14
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'Per records received this is correct as reported ' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	26 Jan 2021 20:05:38
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected 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)	18 Jan 2021 03:22:18
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:17:00
User entered 'AE-Syncopal Episode'	Alyssa-Kay Peay (b) (4) (b) (4)	01 Oct 2020 16:44:01

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:01:20

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:17:00
User entered '5'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:44:01
	(b) (4)	

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:01:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:17:00
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:44:01
	(b) (4)	

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:01:20**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:17:00
User entered empty.	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:44:01
	(b) (4)	



US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:01:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:17:00
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:44:01
	(b) (4)	

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:01:20**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:17:00
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	01 Oct 2020 16:44:01

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:01:20**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:17:00
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:44:01
	(b) (4)	

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:01:20**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:17:00
User entered empty.	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:44:01
	(b) (4)	

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:01:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:35:07
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'Subject was discharged with this med as a result of the AE' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	13 Nov 2020 14:04:26
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 09:32:04
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:17:00
User entered '24 Sep 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	01 Oct 2020 16:44:01

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:01:20**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:17:00
User entered '0'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:44:01
	(b) (4)	

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:01:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:17:00
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:44:01
	(b) (4)	

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:01:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:17:00
User entered empty.	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:44:01
	(b) (4)	



US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:01:20**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:17:00
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:44:01
	(b) (4)	

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:01:20**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 16:44:01

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:01:20**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 16:44:01

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:01:20**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 16:44:01

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:01:20

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:18:56
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: SODIUM, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 09:03:38
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 09:03:38
	(b) (4)	
Data point term sent to Coder	System	01 Oct 2020 16:46:31
User entered 'Sodium Chloride'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:45:37
	(b) (4)	

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:01:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:18:56
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:45:37
	(b) (4)	

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:01:20

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:18:56
User entered 'AE-Hyponatremia'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:45:37
	(b) (4)	

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:01:20**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:18:56
User entered 'I'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:45:37
	(b) (4)	



US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:01:20

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:18:56
User entered 'g (g)'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:45:37
	(b) (4)	

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:01:20**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:18:56
User entered empty.	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:45:37
	(b) (4)	

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:01:20

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:18:56
User entered 'three times daily (TID)'	Alyssa-Kay Peay (b) (4) (b) (4)	01 Oct 2020 16:45:37

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:01:20

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:18:56
User entered empty.	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:45:37
	(b) (4)	

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:01:20**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:18:56
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:45:37
	(b) (4)	

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:01:20**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:18:56
User entered empty.	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:45:37
	(b) (4)	

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:01:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:35:15
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'Med was given on discharge to treat the ongoing condition' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	13 Nov 2020 14:05:37
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 09:32:20
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:18:56
User entered '24 Sep 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	01 Oct 2020 16:45:37

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:01:20**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:18:56
User entered '0'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:45:37
	(b) (4)	



US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:01:20

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:18:56
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:45:37
	(b) (4)	

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:01:20**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:18:56
User entered empty.	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:45:37
	(b) (4)	

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:01:20**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 20:18:56
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:45:37
	(b) (4)	

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:01:20**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	01 Oct 2020 16:45:37

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:01:20**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 16:45:37

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:01:20**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 16:45:37

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:01:20

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:47:42
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 20:19:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: OTHER DIURETICS, ATC: VASOPRESSIN ANTAGONISTS, PRODUCT: TOLVAPTAN, PRODUCTSYNONYM: SAMSCA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 16:48:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 16:48:48
Data point term sent to Coder	System	01 Oct 2020 16:47:33
User entered 'Samsca'	Alyssa-Kay Peay (b) (4) (b) (4)	01 Oct 2020 16:46:45

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:01:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:47:42
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:19:25
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:46:45



US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:01:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:47:42
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
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)	10 Feb 2021 10:04:42
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 'Please review log line #3' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	08 Feb 2021 20:26:21
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 05:23:45
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:19:25
User entered 'AE- Hyponatremia'	Alyssa-Kay Peay (b) (4) (b) (4)	01 Oct 2020 16:46:45

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:01:20

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:47:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:28:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 10:04:18
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).	Danyel Johnson (b) (4) (b) (4)	08 Feb 2021 20:30:36
DataPoint Un-verified.	Danyel Johnson (b) (4) (b) (4)	08 Feb 2021 20:28:47
User entered '30' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	08 Feb 2021 20:28:47
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 05:23:59
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:19:25
User entered '1'	Alyssa-Kay Peay (b) (4) (b) (4)	01 Oct 2020 16:46:45

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:01:20

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:47:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:28:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Un-verified.	(b) (4)	
	Danyel Johnson (b) (4)	08 Feb 2021 20:28:47
User entered 'mg (mg)' reason for change: Per Query Resolution	(b) (4)	
	Danyel Johnson (b) (4)	08 Feb 2021 20:28:47
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:19:25
User entered 'tablet (TABLET)' reason for change: Per Query Resolution	Alyssa-Kay Peay (b) (4)	21 Oct 2020 13:44:49
	(b) (4)	
User entered 'Other (OTHER)'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:46:45
	(b) (4)	

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:01:20

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:47:42
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User closed query 'Per CDM: If dose unit is Other, specify is recorded as "Dose", which is inappropriate. Please update the Dose Unit of this medication to include measuring unit for this ConMed (Like: tablet/ pill/ mg/ ml). (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 15:09:38
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:19:25
Query 'Per CDM: If dose unit is Other, specify is recorded as "Dose", which is inappropriate. Please update the Dose Unit of this medication to include measuring unit for this ConMed (Like: tablet/ pill/ mg/ ml).' answered with 'updated per query ' (Site from DM).	Alyssa-Kay Peay (b) (4) (b) (4)	21 Oct 2020 13:44:58
User entered empty; reason for change Per Query Resolution	Alyssa-Kay Peay (b) (4) (b) (4)	21 Oct 2020 13:44:49
User opened query 'Per CDM: If dose unit is Other, specify is recorded as "Dose", which is inappropriate. Please update the Dose Unit of this medication to include measuring unit for this ConMed (Like: tablet/ pill/ mg/ ml). (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 16:30:52
User entered 'dose'	Alyssa-Kay Peay (b) (4) (b) (4)	01 Oct 2020 16:46:45

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:01:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:47:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:29:00
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Feb 2021 20:30:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Feb 2021 20:30:56
User entered 'once (ONCE)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	08 Feb 2021 20:30:56
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Feb 2021 20:30:45
DataPoint Un-verified.	System	08 Feb 2021 20:30:45
User entered empty; reason for change Data Entry Error	Danyel Johnson (b) (4)	08 Feb 2021 20:30:45
DataPoint Verified.	(b) (4)	08 Feb 2021 20:30:45
User entered 'unknown (UNKNOWN)'	(b) (4), (b) (6)	27 Oct 2020 20:19:25
	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:46:45
	(b) (4)	

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:01:20

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:47:42
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:19:25
User entered empty.	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:46:45

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:01:20

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:47:42
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:19:25
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:46:45

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:01:20**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:47:42
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:19:25
User entered empty.	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:46:45



US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:01:20**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:47:42
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:19:25
User entered '21 Sep 2020'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:46:45

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:01:20**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:47:42
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:19:25
User entered '0'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:46:45

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:01:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:47:42
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:19:25
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:46:45

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:01:20**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:47:42
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:19:25
User entered '21 Sep 2020'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:46:45

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:01:20**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:47:42
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 20:19:25
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	01 Oct 2020 16:46:45

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:01:20**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:47:42
User entered empty.	System	01 Oct 2020 16:46:45

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:01:20**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:47:42
User entered empty.	System	01 Oct 2020 16:46:45

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:01:20**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:47:42
User entered empty.	System	01 Oct 2020 16:46:45



US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:01:20

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:46:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN W/OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Nov 2020 07:06:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Nov 2020 07:06:48
Data point term sent to Coder	System	11 Nov 2020 16:32:17
User entered 'Oxycodone-Acetaminophen (7.5mg-325mg)'	Danyel Johnson (b) (4)	11 Nov 2020 16:31:23

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:01:20

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:46:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'No (N)'	Danyel Johnson (b) (4)	11 Nov 2020 16:31:23

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:01:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:46:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
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).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:42:56
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 'please review AE log line #2' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	08 Feb 2021 20:32:39
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)	19 Jan 2021 05:20:33
User entered 'post surgical pain'	Danyel Johnson (b) (4) (b) (4)	11 Nov 2020 16:31:23

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:01:20**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:46:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '2'	Danyel Johnson (b) (4)	11 Nov 2020 16:31:23

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:01:20**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:46:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'tablet (TABLET)'	Danyel Johnson (b) (4)	11 Nov 2020 16:31:23

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:01:20**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:46:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered empty.	Danyel Johnson (b) (4)	11 Nov 2020 16:31:23

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:01:20

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:46:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'other (OTHER)' reason for change:	(b) (4)	
Data Entry Error	Danyel Johnson (b) (4)	09 Feb 2021 16:28:43
User entered 'as needed (PRN)'	(b) (4)	
	Danyel Johnson (b) (4)	11 Nov 2020 16:31:23
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:01:20

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:46:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'Every 4-6 hours as needed' reason for change: Data Entry Error	(b) (4)	
	Danyel Johnson (b) (4)	09 Feb 2021 16:28:43
User entered empty.	(b) (4)	
	Danyel Johnson (b) (4)	11 Nov 2020 16:31:23
	(b) (4)	



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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:01:20**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:46:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'Oral (ORAL)'	Danyel Johnson (b) (4)	11 Nov 2020 16:31:23

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:01:20**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:46:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered empty.	Danyel Johnson (b) (4)	11 Nov 2020 16:31:23

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:01:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:46:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '21 Sep 2020'	Danyel Johnson (b) (4)	11 Nov 2020 16:31:23

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:01:20**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:46:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '0'	Danyel Johnson (b) (4)	11 Nov 2020 16:31:23

US3832055

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:01:20

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:46:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'No (N)'	Danyel Johnson (b) (4)	11 Nov 2020 16:31:23

US3832055

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:01:20**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:46:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '29 Sep 2020'	Danyel Johnson (b) (4)	11 Nov 2020 16:31:23

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:01:20**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:46:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'No (N)'	Danyel Johnson (b) (4)	11 Nov 2020 16:31:23

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:01:20**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:46:48
User entered empty.	System	11 Nov 2020 16:31:23



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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:01:20**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:46:48
User entered empty.	System	11 Nov 2020 16:31:23

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:01:20**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 13:46:48
User entered empty.	System	11 Nov 2020 16:31:23

US3832055

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 10 Jun 2021 10:01:20**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:42
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'Yes (Y)'	(b) (4) Danyel Johnson (b) (4)	11 Nov 2020 16:27:26

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**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 10:01:20**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:28:06
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:22:12
User entered '22 Sep 2020'	Danyel Johnson (b) (4)	11 Nov 2020 16:29:07
	(b) (4)	

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**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 10:01:20**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:28:02
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:22:12
User entered 'open reduction, internal fixation of the right zygomaticomaxillary complex fracture.'	Danyel Johnson (b) (4)	11 Nov 2020 16:29:07
	(b) (4)	

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**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 10:01:20**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:28:05
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:22:12
User entered 'Adverse Event (AE)'	Danyel Johnson (b) (4)	11 Nov 2020 16:29:07
	(b) (4)	

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**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 10:01:20**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:28:00
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:22:12
User entered empty.	Danyel Johnson (b) (4)	11 Nov 2020 16:29:07
	(b) (4)	

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**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 10:01:20**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '20 Sep 2020'	Danyel Johnson (b) (4)	09 Feb 2021 16:20:33



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:01:20

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'CT of Facial Bones'	Danyel Johnson (b) (4)	09 Feb 2021 16:20:33

US3832055

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:01:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'Adverse Event (AE)'	Danyel Johnson (b) (4)	09 Feb 2021 16:20:33

US3832055

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:01:20

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered empty.	Danyel Johnson (b) (4)	09 Feb 2021 16:20:33

US3832055

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 10 Jun 2021 10:01:20**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '20 Sep 2020'	Danyel Johnson (b) (4)	09 Feb 2021 16:25:12

US3832055

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:01:20

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'HYPONATREMIA CHLORIDE LEVELS'	Danyel Johnson (b) (4)	09 Feb 2021 16:25:12

US3832055

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:01:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'Adverse Event (AE)'	Danyel Johnson (b) (4)	09 Feb 2021 16:25:12

US3832055

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 10 Jun 2021 10:01:20**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered empty.	Danyel Johnson (b) (4)	09 Feb 2021 16:25:12

US3832055

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 10 Jun 2021 10:01:20**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:45
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '21 Sep 2020'	Danyel Johnson (b) (4)	09 Feb 2021 16:25:30



US3832055

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:01:20

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:45
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'HYPONATREMIA CHLORIDE LEVELS'	Danyel Johnson (b) (4)	09 Feb 2021 16:25:30

US3832055

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:01:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:45
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'Adverse Event (AE)'	Danyel Johnson (b) (4)	09 Feb 2021 16:25:30

US3832055

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 10:01:20

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:45
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered empty.	Danyel Johnson (b) (4)	09 Feb 2021 16:25:30

US3832055

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (5)**

**Generated On: 10 Jun 2021 10:01:20**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:51
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '22 Sep 2020'	Danyel Johnson (b) (4)	09 Feb 2021 16:25:49

US3832055

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:01:20

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:51
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'HYPONATREMIA CHLORIDE LEVELS'	Danyel Johnson (b) (4)	09 Feb 2021 16:25:49

US3832055

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:01:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:51
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'Adverse Event (AE)'	Danyel Johnson (b) (4)	09 Feb 2021 16:25:49

US3832055

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:01:20

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:51
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered empty.	Danyel Johnson (b) (4)	09 Feb 2021 16:25:49

US3832055

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 10:01:20

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '20 Aug 2020'	Danyel Johnson (b) (4)	09 Feb 2021 16:26:21



US3832055

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 10:01:20

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'ekg'	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 16:26:21

US3832055

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 10:01:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'Adverse Event (AE)'	Danyel Johnson (b) (4)	09 Feb 2021 16:26:21

US3832055

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 10:01:20

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:29:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered empty.	Danyel Johnson (b) (4)	09 Feb 2021 16:26:21

US3832055

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (7)**

**Generated On: 10 Jun 2021 10:01:20**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:32
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:06:26
User entered '20 Aug 2020'	Danyel Johnson (b) (4)	23 Feb 2021 20:50:39

US3832055

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 10:01:20

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:32
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:06:26
User entered 'CT Scan of Neck and Spine'	Danyel Johnson (b) (4)	23 Feb 2021 20:50:39

US3832055

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 10:01:20

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:32
User closed query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 09:29:26
Query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'Related to AE log line #1' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	19 Mar 2021 16:14:51
User opened query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 22:16:50
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	08 Mar 2021 12:06:26
User entered 'Adverse Event (AE)'	Danyel Johnson (b) (4) (b) (4)	23 Feb 2021 20:50:39

US3832055

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 10:01:20

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:37:32
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:06:26
User entered empty.	Danyel Johnson (b) (4)	23 Feb 2021 20:50:39

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered		
'USA-US100-2020-MRNA-1273-P301000004'	System	24 Sep 2020 01:46:04



**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'Yes (Y)'	System	24 Sep 2020 01:46:04

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'No (N)'	System	24 Sep 2020 01:46:04

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'No (N)'	System	24 Sep 2020 01:46:04

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'Yes (Y)'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'No (N)'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'No (N)'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'No (N)'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'Gowdhami'	System	24 Sep 2020 01:46:04



US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'Mohan'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered '1655 E. Greenville St'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'Anderson'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'SC'	System	24 Sep 2020 01:46:04

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered '29621'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 18:12:44
User entered 'US'	System	24 Sep 2020 01:59:40

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
	(b) (4)	
User entered '6'	System	10 Feb 2021 14:20:06
User entered '5'	System	04 Dec 2020 17:41:02
User entered '4'	System	04 Dec 2020 14:10:49
User entered '3'	System	12 Nov 2020 15:16:43
User entered '2'	System	24 Sep 2020 18:12:57
User entered '1'	System	24 Sep 2020 01:59:40

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered		
'USA-US100-2020-MRNA-1273-P301000004'	System	24 Sep 2020 01:46:04



**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'Yes (Y)'	System	24 Sep 2020 01:46:04

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'No (N)'	System	24 Sep 2020 01:46:04

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'No (N)'	System	24 Sep 2020 01:46:04

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'Yes (Y)'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'No (N)'	System	24 Sep 2020 01:46:04

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'No (N)'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'No (N)'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'Gowdhami'	System	24 Sep 2020 01:46:04



US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'Mohan'	System	24 Sep 2020 01:46:04

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered '1655 E. Greenville St'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'Anderson'	System	24 Sep 2020 01:46:04

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'SC'	System	24 Sep 2020 01:46:04

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered '29621'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 18:12:44
User entered 'US'	System	24 Sep 2020 01:59:40

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
	(b) (4)	
User entered '6'	System	10 Feb 2021 14:20:06
User entered '5'	System	04 Dec 2020 17:41:02
User entered '4'	System	04 Dec 2020 14:10:49
User entered '3'	System	12 Nov 2020 15:16:43
User entered '2'	System	24 Sep 2020 18:12:57
User entered '1'	System	24 Sep 2020 01:59:40

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 10:01:20**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:33:11
User entered '23/Sep/2020 21:59'	System	24 Sep 2020 01:59:40



US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:01:20

**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.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 18:12:44
User entered 'I'	(b) (4), (b) (6)	24 Sep 2020 01:59:40

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered		
'USA-US100-2020-MRNA-1273-P301000004'	System	24 Sep 2020 01:46:04

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'Yes (Y)'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

Death

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'No (N)'	System	24 Sep 2020 01:46:04

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'No (N)'	System	24 Sep 2020 01:46:04

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'Yes (Y)'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'No (N)'	System	24 Sep 2020 01:46:04

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'No (N)'	System	24 Sep 2020 01:46:04



US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'No (N)'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'Gowdhami'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'Mohan'	System	24 Sep 2020 01:46:04

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered '1655 E. Greenville St'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'Anderson'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'SC'	System	24 Sep 2020 01:46:04

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered '29621'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 18:12:44
User entered 'US'	System	24 Sep 2020 01:59:40



US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
	(b) (4)	
User entered '6'	System	10 Feb 2021 14:20:06
User entered '5'	System	04 Dec 2020 17:41:02
User entered '4'	System	04 Dec 2020 14:10:49
User entered '3'	System	12 Nov 2020 15:16:43
User entered '2'	System	24 Sep 2020 18:12:57
User entered '1'	System	24 Sep 2020 01:59:40

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 10:01:20**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:33:11
User entered '24/Sep/2020 14:12'	System	24 Sep 2020 18:12:57

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:01:20

**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.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 15:16:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 19:33:11
User entered 'I'	(b) (4), (b) (6)	24 Sep 2020 18:12:57

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered		
'USA-US100-2020-MRNA-1273-P301000004'	System	24 Sep 2020 01:46:04

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'Yes (Y)'	System	24 Sep 2020 01:46:04

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'No (N)'	System	24 Sep 2020 01:46:04

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'No (N)'	System	24 Sep 2020 01:46:04

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'Yes (Y)'	System	24 Sep 2020 01:46:04



US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'No (N)'	System	24 Sep 2020 01:46:04

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'No (N)'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'No (N)'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'Gowdhami'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'Mohan'	System	24 Sep 2020 01:46:04

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered '1655 E. Greenville St'	System	24 Sep 2020 01:46:04

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'Anderson'	System	24 Sep 2020 01:46:04

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'SC'	System	24 Sep 2020 01:46:04



**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered '29621'	System	24 Sep 2020 01:46:04

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 18:12:44
User entered 'US'	System	24 Sep 2020 01:59:40

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
	(b) (4)	
User entered '6'	System	10 Feb 2021 14:20:06
User entered '5'	System	04 Dec 2020 17:41:02
User entered '4'	System	04 Dec 2020 14:10:49
User entered '3'	System	12 Nov 2020 15:16:43
User entered '2'	System	24 Sep 2020 18:12:57
User entered '1'	System	24 Sep 2020 01:59:40

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:01:20

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:59:33
User entered '12/Nov/2020 10:16'	System	12 Nov 2020 15:16:43

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:01:20

**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.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 14:10:40
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:59:35
User entered 'I'	(b) (4), (b) (6)	12 Nov 2020 15:16:43

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered	System	24 Sep 2020 01:46:04
'USA-US100-2020-MRNA-1273-P301000004'		

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'Yes (Y)'	System	24 Sep 2020 01:46:04

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'No (N)'	System	24 Sep 2020 01:46:04



**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'No (N)'	System	24 Sep 2020 01:46:04

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'Yes (Y)'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'No (N)'	System	24 Sep 2020 01:46:04

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'No (N)'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'No (N)'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'Gowdhami'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'Mohan'	System	24 Sep 2020 01:46:04

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered '1655 E. Greenville St'	System	24 Sep 2020 01:46:04



US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'Anderson'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'SC'	System	24 Sep 2020 01:46:04

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered '29621'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 18:12:44
User entered 'US'	System	24 Sep 2020 01:59:40

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
	(b) (4)	
User entered '6'	System	10 Feb 2021 14:20:06
User entered '5'	System	04 Dec 2020 17:41:02
User entered '4'	System	04 Dec 2020 14:10:49
User entered '3'	System	12 Nov 2020 15:16:43
User entered '2'	System	24 Sep 2020 18:12:57
User entered '1'	System	24 Sep 2020 01:59:40

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 10:01:20**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:11:31
User entered '04/Dec/2020 14:10'	System	04 Dec 2020 14:10:49

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:01:20

**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.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 18:11:36
Reviewed for Safety.	(b) (4), (b) (6)	04 Dec 2020 17:40:51
User entered 'I'	(b) (4), (b) (6)	04 Dec 2020 14:10:49

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered		
'USA-US100-2020-MRNA-1273-P301000004'	System	24 Sep 2020 01:46:04



**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'Yes (Y)'	System	24 Sep 2020 01:46:04

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'No (N)'	System	24 Sep 2020 01:46:04

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'No (N)'	System	24 Sep 2020 01:46:04

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'Yes (Y)'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'No (N)'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'No (N)'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'No (N)'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'Gowdhami'	System	24 Sep 2020 01:46:04



US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'Mohan'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered '1655 E. Greenville St'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'Anderson'	System	24 Sep 2020 01:46:04

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'SC'	System	24 Sep 2020 01:46:04

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered '29621'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 18:12:44
User entered 'US'	System	24 Sep 2020 01:59:40

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
	(b) (4)	
User entered '6'	System	10 Feb 2021 14:20:06
User entered '5'	System	04 Dec 2020 17:41:02
User entered '4'	System	04 Dec 2020 14:10:49
User entered '3'	System	12 Nov 2020 15:16:43
User entered '2'	System	24 Sep 2020 18:12:57
User entered '1'	System	24 Sep 2020 01:59:40

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form (5)**

**Generated On: 10 Jun 2021 10:01:20**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:18:42
User entered '04/Dec/2020 17:41'	System	04 Dec 2020 17:41:02



US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 10:01:20

**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.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 14:19:40
DataPoint Verified.	(b) (4), (b) (6)	21 Jan 2021 18:18:43
User entered 'I'	(b) (4), (b) (6)	04 Dec 2020 17:41:02

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered		
'USA-US100-2020-MRNA-1273-P301000004'	System	24 Sep 2020 01:46:04

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'Yes (Y)'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

Death

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'No (N)'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'No (N)'	System	24 Sep 2020 01:46:04

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'Yes (Y)'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'No (N)'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'No (N)'	System	24 Sep 2020 01:46:04



US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'No (N)'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'Gowdhami'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'Mohan'	System	24 Sep 2020 01:46:04

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered '1655 E. Greenville St'	System	24 Sep 2020 01:46:04

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'Anderson'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered 'SC'	System	24 Sep 2020 01:46:04

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:01:20**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 01:59:33
User entered '29621'	System	24 Sep 2020 01:46:04

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 19:33:11
Reviewed for Safety.	(b) (4), (b) (6)	24 Sep 2020 18:12:44
User entered 'US'	System	24 Sep 2020 01:59:40



US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:01:20

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
	(b) (4)	
User entered '6'	System	10 Feb 2021 14:20:06
User entered '5'	System	04 Dec 2020 17:41:02
User entered '4'	System	04 Dec 2020 14:10:49
User entered '3'	System	12 Nov 2020 15:16:43
User entered '2'	System	24 Sep 2020 18:12:57
User entered '1'	System	24 Sep 2020 01:59:40

**US3832055**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000004**

**Form: Safety Report Form (6)**

**Generated On: 10 Jun 2021 10:01:20**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:28:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered '10/Feb/2021 09:20'	(b) (4) System	10 Feb 2021 14:20:06

US3832055

Folder: SAE USA-US100-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 10:01:20

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:28:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:59:42
User entered 'I'	(b) (4), (b) (6)	10 Feb 2021 14:20:06