

US3842060 (Prod: New Jersey Medical School)

Generated By: KC Joubran

Generated On: 12 Aug 2021 13:35:38

All time stamps listed in this document are displayed in GMT

US3842060

Form: Participant Creation

Data signed: (b) (4) 16 Feb 2021 18:57:13

Generated On: 12 Aug 2021 13:35:38

---

[Participant ID](#)

US3842060

---

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

---

---

US3842060

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 18:57:13

Generated On: 12 Aug 2021 13:35:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 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	SCRN

US3842060

Folder: Screening

Form: Demographics

Data signed: (b) (4) 16 Feb 2021 18:57:12

Generated On: 12 Aug 2021 13:35:38

Date of Birth (MMM yyyy)	(b) (6) 1963
Age	57
Age Units	YEARS
Age (Derived)	57
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	True
If race is Other, specify	CUBAN
Unknown	False
Not reported	False

US3842060

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 16 Feb 2021 18:57:12

Generated On: 12 Aug 2021 13:35:38

Date of Informed Consent ( <i>dd MMM yyyy</i> )	21 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input checked="" 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

US3842060

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 16 Feb 2021 18:57:12

Generated On: 12 Aug 2021 13:35:38

---

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

---

US3842060

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 16 Feb 2021 18:57:12

Generated On: 12 Aug 2021 13:35:38

---

Were any significant conditions reported?

Yes ☒

No ☐

---

US3842060

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 23 Mar 2021 15:56:39

Generated On: 12 Aug 2021 13:35:38

Condition	SEASONAL RHINITIS (ALLERGIC)
Start date (dd MMM yyyy)	UN UNK 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



US3842060

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 23 Mar 2021 15:56:39

Generated On: 12 Aug 2021 13:35:38

Condition	HERNIATED DISK T10 T11
Start date (dd MMM yyyy)	UN UNK 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

US3842060

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 23 Mar 2021 15:56:39

Generated On: 12 Aug 2021 13:35:38

Condition	RIGHT ROTATOR CUFF SURGERY
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

US3842060

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 23 Mar 2021 15:56:39

Generated On: 12 Aug 2021 13:35:38

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

US3842060

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 23 Mar 2021 15:56:39

Generated On: 12 Aug 2021 13:35:38

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

US3842060

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 18:57:13

Generated On: 12 Aug 2021 13:35:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	21 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	13:09 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 13:09
Height ( <i>xxx.x</i> )	174.5 cm
Weight ( <i>xxx.x</i> )	88.3 kg
BMI ( <i>xxx.x</i> )	28.99812 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)	

US3842060

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 18:57:12

Generated On: 12 Aug 2021 13:35:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 OCT 2020

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

US3842060

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 16 Feb 2021 18:57:13

Generated On: 12 Aug 2021 13:35:38

---

**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☒ No ☐

---

**Specify**

**CORRECTIONS**

---

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

**No Risk Identified** False

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

US3842060

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 16 Feb 2021 18:57:13

Generated On: 12 Aug 2021 13:35:38

<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)	True
<b>Other</b>	False
<b>Specify</b>	



US3842060

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 18:57:13

Generated On: 12 Aug 2021 13:35:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 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	VISIT1

US3842060

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 16 Feb 2021 18:57:13

Generated On: 12 Aug 2021 13:35:38

What was the date of randomization? (dd MMM yyyy) 21 OCT 2020

What was the participant's randomization number? 117719

In what Cohort was the participant enrolled?   
 >=18 and <65 years and not at risk ☒   
 >=18 and <65 years and at risk ☐   
 >=65 years ☐

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Feb 2021 18:57:13

Generated On: 12 Aug 2021 13:35:38

Height	
Weight	

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 18:57:13

Generated On: 12 Aug 2021 13:35:38

Height	
Weight	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 OCT 2020
Time of assessment (00:00-23:59)	13:09 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 13:09
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)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 18:57:13

Generated On: 12 Aug 2021 13:35:38

Height	
Weight	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 OCT 2020
Time of assessment (00:00-23:59)	16:11 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 16:11
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3842060

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 18:57:12

Generated On: 12 Aug 2021 13:35:38

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3842060

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 18:57:12

Generated On: 12 Aug 2021 13:35:38

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐  
Physician withheld dose due to Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by Participant ☐  
Confirmed COVID-19 ☐  
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 21 OCT 2020

What was the treatment time? (00:00-23:59) 15:40 (24 HR)

Treatment Date and Time (derived) 21 OCT 2020 15:40

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

US3842060

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 18:57:12

Generated On: 12 Aug 2021 13:35:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 OCT 2020

Collection time (00:00-23:59)

13:52 (24 HR)

Collection date and time (derived)

21 OCT 2020 13:52



US3842060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 18:57:12

Generated On: 12 Aug 2021 13:35:38

Collection date (dd MMM yyyy)			21 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:58	21 OCT 2020 13:58
Nasopharyngeal Swab 2	No		

US3842060

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:57:12

Generated On: 12 Aug 2021 13:35:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 OCT 2020 16:16

PC Open Date & Time

21 OCT 2020 16:00

PC Close Date & Time

21 OCT 2020 18:30

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	21 OCT 2020 20:17
PC Open Date & Time	21 OCT 2020 19:25
PC Close Date & Time	22 OCT 2020 11:59

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

22 OCT 2020 17:12

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:35:38

---

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 OCT 2020 12:03

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:35:38

---

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp 24 OCT 2020 13:01

PC Open Date & Time 24 OCT 2020 12:00

PC Close Date & Time 25 OCT 2020 11:59

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:35:38

---

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

96.2 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

25 OCT 2020 13:11

---

PC Open Date & Time

25 OCT 2020 12:00

---

PC Close Date & Time

26 OCT 2020 11:59

---



US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

95.9 °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

26 OCT 2020 16:38

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **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

27 OCT 2020 19:00

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:35:38

**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

21 OCT 2020 16:20

PC Open Date & Time

21 OCT 2020 16:00

PC Close Date & Time

21 OCT 2020 18:30

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

21 OCT 2020 20:18

PC Open Date & Time

21 OCT 2020 19:25

PC Close Date & Time

22 OCT 2020 11:59

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

22 OCT 2020 17:12

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

23 OCT 2020 12:03

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

24 OCT 2020 13:01

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

25 OCT 2020 13:12

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59



US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

26 OCT 2020 16:39

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

27 OCT 2020 19:01

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:35:38

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

No ☒

Yes ☐

PC Time stamp	21 OCT 2020 16:21
PC Open Date & Time	21 OCT 2020 16:00
PC Close Date & Time	21 OCT 2020 18:30

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:35:38

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

No ☒

Yes ☐

PC Time stamp	21 OCT 2020 20:19
PC Open Date & Time	21 OCT 2020 19:25
PC Close Date & Time	22 OCT 2020 11:59

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:35:38

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

46 of 1624

EAB) (1725)

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:35:38

Yes <input type="checkbox"/>	
PC Time stamp	22 OCT 2020 17:13
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59



US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

48 of 1624

EAB) (1725)

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:35:38

		Yes <input type="checkbox"/>
PC Time stamp	23 OCT 2020 12:04	
PC Open Date & Time	23 OCT 2020 12:00	
PC Close Date & Time	24 OCT 2020 11:59	

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:35:38

Yes <input type="checkbox"/>	
PC Time stamp	24 OCT 2020 13:02
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:35:38

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

52 of 1624

EAB) (1725)

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:35:38

Yes <input type="checkbox"/>	
PC Time stamp	25 OCT 2020 13:12
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:35:38

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

54 of 1624

EAB) (1725)

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:35:38

Yes <input type="checkbox"/>	
PC Time stamp	26 OCT 2020 16:39
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59



US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

56 of 1624

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:35:38

Yes <input type="checkbox"/>	
PC Time stamp	27 OCT 2020 19:02
PC Open Date & Time	27 OCT 2020 12:00
PC Close Date & Time	28 OCT 2020 11:59

US3842060

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:57:13

Generated On: 12 Aug 2021 13:35:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3842060

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:57:12

Generated On: 12 Aug 2021 13:35:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3842060

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:57:13

Generated On: 12 Aug 2021 13:35:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3842060

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:57:12

Generated On: 12 Aug 2021 13:35:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3842060

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:57:13

Generated On: 12 Aug 2021 13:35:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3842060

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:57:12

Generated On: 12 Aug 2021 13:35:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3842060

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 18:57:13

Generated On: 12 Aug 2021 13:35:38

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

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 18:57:13

Generated On: 12 Aug 2021 13:35:38

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 NOV 2020
Time of assessment (00:00-23:59)	14:21 (24 HR)
Vital Signs Date and Time (derived)	18 NOV 2020 14:21
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 18:57:13

Generated On: 12 Aug 2021 13:35:38

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Date of assessment (dd MMM yyyy)	
Time of assessment (00:00-23:59)	
Vital Signs Date and Time (derived)	
Temperature (xxx.x)	
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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	

US3842060

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 18:57:12

Generated On: 12 Aug 2021 13:35:38

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3842060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 18:57:12

Generated On: 12 Aug 2021 13:35:38

Was study treatment given? Yes ☐ No ☒

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☒

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

PROTOCOL DIRECTIVE VIA EPIP HAS REQUESTED THAT 2ND DOSE NOT BE ADMINISTERED. PARTICIPANT HAD A POSITIVE SALIVA TEST THAT WAS ADMINISTERED AT HIS WORKSITE.

What was the study treatment? \_\_\_\_\_

What was the treatment date? (dd MMM yyyy) \_\_\_\_\_

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

Treatment Date and Time (derived) \_\_\_\_\_

Which arm was used to give treatment? Left Arm ☐

Right Arm ☐

What was the frequency of the study treatment dosing? \_\_\_\_\_

What was the route of administration for the study treatment? \_\_\_\_\_

US3842060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 18:57:12

Generated On: 12 Aug 2021 13:35:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

18 NOV 2020

Collection time (00:00-23:59)

14:40 (24 HR)

Collection date and time (derived)

18 NOV 2020 14:40

US3842060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 18:57:12

Generated On: 12 Aug 2021 13:35:38

Collection date (dd MMM yyyy)			18 NOV 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:42	18 NOV 2020 14:42
Nasopharyngeal Swab 2	No		

US3842060

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:57:12

Generated On: 12 Aug 2021 13:35:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3842060

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:57:13

Generated On: 12 Aug 2021 13:35:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3842060

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:57:12

Generated On: 12 Aug 2021 13:35:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3842060

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:57:13

Generated On: 12 Aug 2021 13:35:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3842060

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:57:12

Generated On: 12 Aug 2021 13:35:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3842060

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:57:13

Generated On: 12 Aug 2021 13:35:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3842060

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:57:12

Generated On: 12 Aug 2021 13:35:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3842060

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 18:57:13

Generated On: 12 Aug 2021 13:35:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 DEC 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

US3842060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 18:57:13

Generated On: 12 Aug 2021 13:35:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	16 DEC 2020
Time of assessment ( <i>00:00-23:59</i> )	11:43 (24 HR)
Vital Signs Date and Time (derived)	16 DEC 2020 11:43
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> )	86 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3842060

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 18:57:13

Generated On: 12 Aug 2021 13:35:38

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3842060

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 18:57:12

Generated On: 12 Aug 2021 13:35:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 DEC 2020

Collection time (00:00-23:59)

11:52 (24 HR)

Collection date and time (derived)

16 DEC 2020 11:52

US3842060

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:57:12

Generated On: 12 Aug 2021 13:35:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

TIMEPOINT	DAY 61
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	18 DEC 2020 08:29:54
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

TIMEPOINT	DAY 68
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	25 DEC 2020 19:33:43
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

TIMEPOINT	DAY 75
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	01 JAN 2021 00:13:57
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 82

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 05:10:53

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 08:47:12
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59



US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

22 JAN 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

26 JAN 2021 23:59

---

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 103

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

29 JAN 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

02 FEB 2021 23:59

---

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	13 FEB 2021 12:04:43
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 FEB 2021 12:01:14
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59



US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 FEB 2021 17:40:26

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 MAR 2021 05:52:49

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	12 MAR 2021 05:14:55
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 MAR 2021 05:20:35

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 MAR 2021 05:32:43

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 APR 2021 05:59:24

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 05:56:58

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 APR 2021 05:57:52

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59



US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 APR 2021 05:21:13

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 05:33:58

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

07 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

11 MAY 2021 23:59

---

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

21 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

25 MAY 2021 23:59

---



US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 222

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

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 229

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

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 243

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

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

18 JUN 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

22 JUN 2021 23:59

---



US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 250

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 JUN 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

16 JUL 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

20 JUL 2021 23:59

---



US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 292

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 299

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59



US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 306

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 313

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 320

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 SEP 2021 23:59



US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

17 SEP 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

21 SEP 2021 23:59

---

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 OCT 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 355

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

08 OCT 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

12 OCT 2021 23:59

---



US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 OCT 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 376

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 383

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

05 NOV 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

09 NOV 2021 23:59

---



US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

19 NOV 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

23 NOV 2021 23:59

---

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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°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="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"/>

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 411

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59



US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 418

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 DEC 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 DEC 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59



US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59



US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 474

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

04 FEB 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

08 FEB 2022 23:59

---

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

11 FEB 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

15 FEB 2022 23:59

---

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 495

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59



US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

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 ☐

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

11 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

15 MAR 2022 23:59

---

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

18 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

22 MAR 2022 23:59

---

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59



US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 530

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 537

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 544

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59



US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59



US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

10 JUN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

14 JUN 2022 23:59

---

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59



US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

24 JUN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

28 JUN 2022 23:59

---

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

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 ☐

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 635

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 JUL 2022 23:59



US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 656

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

---

Date and time of submission

---

<a href="#">Patient Cloud Open Date &amp; Time</a>	12 AUG 2022 00:01
----------------------------------------------------	-------------------

---

<a href="#">Patient Cloud Close Date &amp; Time</a>	16 AUG 2022 23:59
-----------------------------------------------------	-------------------

---



US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

19 AUG 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

23 AUG 2022 23:59

---

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 677

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

---

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

---



US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

23 SEP 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

27 SEP 2022 23:59

---

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 712

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

07 OCT 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

11 OCT 2022 23:59

---



US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 733

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 747

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59



US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

18 NOV 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

22 NOV 2022 23:59

---

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

25 NOV 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

29 NOV 2022 23:59

---

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

02 DEC 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

06 DEC 2022 23:59

---



US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

09 DEC 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

13 DEC 2022 23:59

---

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

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

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2022 23:59

US3842060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:35:38

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

**US3842060**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 DEC 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 DEC 2022 23:59

US3842060

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 12 Aug 2021 13:35:38

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
Yes	Yes	05 MAR 2021 05:53:29

US3842060

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:57:13

Generated On: 12 Aug 2021 13:35:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3842060

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:57:12

Generated On: 12 Aug 2021 13:35:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3842060

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 19:04:25

Generated On: 12 Aug 2021 13:35:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3842060

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:57:12

Generated On: 12 Aug 2021 13:35:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3842060

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Mar 2021 15:56:39

Generated On: 12 Aug 2021 13:35:38

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 MAR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3842060

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Mar 2021 15:56:39

Generated On: 12 Aug 2021 13:35:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3842060

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Mar 2021 15:56:39

Generated On: 12 Aug 2021 13:35:38

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 MAR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3842060

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 23 Mar 2021 15:56:39

Generated On: 12 Aug 2021 13:35:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3842060**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:35:38**

Was this visit performed? Yes ☐  
No ☐

Visit date (dd MMM yyyy) \_\_\_\_\_

Was visit performed at the participant's home or at the clinic? Home ☐  
Clinic ☐

Folder OID \_\_\_\_\_



US3842060

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

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

US3842060

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:35:38

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

US3842060

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:35:38

Was the sample collected?

Yes ☐

No ☐

Collection date (*dd MMM yyyy*)

Collection time (*00:00-23:59*)

Collection date and time (derived)

**US3842060**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:35:38**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3842060

Folder: Covid-19 Assessment 29 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 16 Feb 2021 18:57:12

Generated On: 12 Aug 2021 13:35:38

Date of Contact	29 OCT 2020
Time of Contact	03:46
Date and Time of Contact (derived)	29 OCT 2020 03:46
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input type="checkbox"/></div> <div>No<input checked="" type="checkbox"/></div>

US3842060

Folder: Covid-19 Assessment 29 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 16 Feb 2021 18:57:12

Generated On: 12 Aug 2021 13:35:38

---

[Generate Next COVID-19 Assessment](#)

Yes ☒  
No ☐

---

US3842060

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

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 18:57:13

Generated On: 12 Aug 2021 13:35:38

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

Visit date (dd MMM yyyy)	13 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
------------	---------------

US3842060

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

Form: Unblinding

Data signed: (b) (4) 23 Mar 2021 15:56:39

Generated On: 12 Aug 2021 13:35:38

Date of updated informed consent ( <i>dd MMM yyyy</i> )	13 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	13 JAN 2021
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	
Continuing with mRNA-1273	1



US3842060

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Feb 2021 18:57:13

Generated On: 12 Aug 2021 13:35:38

Height	
Weight	
BMI (xxx.x)	

US3842060

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 18:57:13

Generated On: 12 Aug 2021 13:35:38

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 JAN 2021
Time of assessment (00:00-23:59)	14:43 (24 HR)
Vital Signs Date and Time (derived)	13 JAN 2021 14:43
Temperature (xxx.x)	99.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3842060

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 18:57:13

Generated On: 12 Aug 2021 13:35:38

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 JAN 2021
Time of assessment (00:00-23:59)	17:18 (24 HR)
Vital Signs Date and Time (derived)	13 JAN 2021 17:18
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3842060

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

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 18:57:13

Generated On: 12 Aug 2021 13:35:38

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3842060

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

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 18:57:12

Generated On: 12 Aug 2021 13:35:38

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 13 JAN 2021

What was the treatment time? (00:00-23:59) 16:43 (24 HR)

Treatment Date and Time (derived) 13 JAN 2021 16:43

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

US3842060

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 18:57:12

Generated On: 12 Aug 2021 13:35:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 JAN 2021

Collection time (00:00-23:59)

15:16 (24 HR)

Collection date and time (derived)

13 JAN 2021 15:16

US3842060

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Feb 2021 18:57:12

Generated On: 12 Aug 2021 13:35:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	13 JAN 2021
-------------------------------	-------------

Collection time (00:00 - 23:59)	15:11
---------------------------------	-------

Collection Date and Time (derived)	13 JAN 2021 15:11
------------------------------------	-------------------

US3842060

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

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:57:12

Generated On: 12 Aug 2021 13:35:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3842060

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:57:13

Generated On: 12 Aug 2021 13:35:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3842060

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:57:12

Generated On: 12 Aug 2021 13:35:38

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

US3842060

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 18:57:13

Generated On: 12 Aug 2021 13:35:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3842060

Folder: OL-D29 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 18:57:13

Generated On: 12 Aug 2021 13:35:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	10 FEB 2021
Time of assessment ( <i>00:00-23:59</i> )	10:54 (24 HR)
Vital Signs Date and Time (derived)	10 FEB 2021 10:54
Temperature ( <i>xxx.x</i> )	99.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	80 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3842060

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 18:57:13

Generated On: 12 Aug 2021 13:35:38

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3842060

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 18:57:12

Generated On: 12 Aug 2021 13:35:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

10 FEB 2021

Collection time (00:00-23:59)

11:06 (24 HR)

Collection date and time (derived)

10 FEB 2021 11:06

US3842060

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 16 Feb 2021 18:57:12

Generated On: 12 Aug 2021 13:35:38

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Mar 2021 15:56:38

Generated On: 12 Aug 2021 13:35:38

AEID	
Adverse event	A-SYMPTOMATIC COVID-19
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	26 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	29 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

311 of 1624



US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Mar 2021 15:56:38

Generated On: 12 Aug 2021 13:35:38

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

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Mar 2021 15:56:38

Generated On: 12 Aug 2021 13:35:38

---

PARTICIPANT POSITIVE ON  
LOCAL SALIVA TEST,  
REPORTED A-SYMPTOMATIC.  
CONFIRMED WITH PPD, PER  
PROTOCOL PARTICIPANT  
DISCONTINUED FROM  
RECEIVING STUDY PRODUCT.  
WILL CONTINUE STUDY  
SCHEDULES AND  
PROCEDURES.

---

Serious Adverse Event Derived (CSA Programming Field Only)	0
------------------------------------------------------------	---

Medically Attended AE Derived (CSA Programming Field Only)	0
------------------------------------------------------------	---

Admitted to ICU Derived (CSA Programming Field Only)	
------------------------------------------------------	--

---

---

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Mar 2021 15:56:38

Generated On: 12 Aug 2021 13:35:38

AEID

Adverse event

ANXIETY R/T  
CLAUSTROPHOBIA

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)

17 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

17 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

314 of 1624

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Mar 2021 15:56:38

Generated On: 12 Aug 2021 13:35:38

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

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Mar 2021 15:56:38

Generated On: 12 Aug 2021 13:35:38

AEID

Adverse event

CLAUSTROPHOBIA

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)

17 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

17 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

316 of 1624

EAB) (1725)

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Mar 2021 15:56:38

Generated On: 12 Aug 2021 13:35:38

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

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 16 Feb 2021 18:57:12

Generated On: 12 Aug 2021 13:35:38

---

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

Yes ☒

No ☐

---

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

---

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 10:36:50

Generated On: 12 Aug 2021 13:35:38

Name of Medication SIMVASTATIN

Prophylaxis Yes ☒  
No ☐

Indication REDUCE RISK OF MI OR BRAIN  
ATTACK

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

319 of 1624



US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 10:36:50

Generated On: 12 Aug 2021 13:35:38

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

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 10:36:50

Generated On: 12 Aug 2021 13:35:38

Name of Medication VITAMIN B12

Prophylaxis Yes ☒  
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

321 of 1624

EAB) (1725)

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 10:36:50

Generated On: 12 Aug 2021 13:35:38

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

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 10:36:50

Generated On: 12 Aug 2021 13:35:38

Name of Medication DIAZEPAM

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY RELATED TO MRI  
INDUCED CLAUSTROPHOBIA

Dose per administration 2.5

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

323 of 1624

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 10:36:50

Generated On: 12 Aug 2021 13:35:38

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	17 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	17 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 10:36:50

Generated On: 12 Aug 2021 13:35:38

Name of Medication ZINC

Prophylaxis Yes ☒  
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

325 of 1624

EAB) (1725)

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 10:36:50

Generated On: 12 Aug 2021 13:35:38

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

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 10:36:50

Generated On: 12 Aug 2021 13:35:38

Name of Medication VITAMIN D

Prophylaxis Yes ☒  
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 50000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

327 of 1624

EAB) (1725)



US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 10:36:50

Generated On: 12 Aug 2021 13:35:38

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

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 10:36:50

Generated On: 12 Aug 2021 13:35:38

Name of Medication BOTOX INJECTIONS

Prophylaxis Yes ☐  
No ☒

Indication NEUROPATHY, FACE (RIGHT SIDE)

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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 90 DAYS

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

329 of 1624

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 10:36:50

Generated On: 12 Aug 2021 13:35:38

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

US3842060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Mar 2021 15:56:38

Generated On: 12 Aug 2021 13:35:38

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3842060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 23 Mar 2021 15:56:38

Generated On: 12 Aug 2021 13:35:38

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
13 JAN 2021	BOTOX ADMINISTRATION TO FACE EVERY 90 DAYS	Other	NEUROPATHY, RIGHT SIDE OF FACE

US3842060

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 16 Feb 2021 18:57:12

Generated On: 12 Aug 2021 13:35:38

Date of dosing discontinuation (dd MMM yyyy) 21 OCT 2020

Primary reason for dosing discontinuation

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

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

US3842060

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 16 Feb 2021 18:57:12

Generated On: 12 Aug 2021 13:35:38

Date of study discontinuation/completion (dd MMM yyyy)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

Audit

US3842060 (Prod: New Jersey Medical School)



**US3842060**

**Form: Participant Creation**

**Generated On: 12 Aug 2021 13:35:38**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'US3842060'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Oct 2020 16:33:42

US3842060

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:35:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Yes (Y)'	Zoraida Cruz (b) (4)	21 Oct 2020 19:13:20
	(b) (4)	

US3842060

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:35:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '21 OCT 2020'	RWS_ENDPOINT	21 Oct 2020 16:33:43
	ENDPOINT (b) (4)	

US3842060

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:35:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Clinic (Clinic)'	Zoraida Cruz (b) (4)	21 Oct 2020 19:13:20
	(b) (4)	

US3842060

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:35:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered 'SCRN'	System	21 Oct 2020 19:13:20

US3842060

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:35:38

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User closed query 'Per GCL Lab Recon: Antibody-mediated Immunogenicity- Sex (Male) and Year of Birth (1963) recorded on this form however same is missing in PPD central lab. Please reconcile the data and update as needed. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 11:27:56
Query 'Per GCL Lab Recon: Antibody-mediated Immunogenicity- Sex (Male) and Year of Birth (1963) recorded on this form however same is missing in PPD central lab. Please reconcile the data and update as needed. Else clarify, thank you.' answered with 'Will notify the missing month of birth to the lab to update.' (Site from DM).	Zoraida Cruz (b) (4) (b) (4)	04 Nov 2020 00:26:35
User opened query 'Per GCL Lab Recon: Antibody-mediated Immunogenicity- Sex (Male) and Year of Birth (1963) recorded on this form however same is missing in PPD central lab. Please reconcile the data and update as needed. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 09:16:21
User entered (b) (6) 1963'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Oct 2020 16:33:44

US3842060

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:35:38

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '57'	Zoraida Cruz (b) (4)	21 Oct 2020 19:13:47
	(b) (4)	

**US3842060**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:35:38**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered 'YEARS'	System	21 Oct 2020 19:13:47



**US3842060**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:35:38**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered '57'	System	21 Oct 2020 19:14:14

US3842060

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:35:38

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Male (M)'	Zoraida Cruz (b) (4)	21 Oct 2020 19:13:47
	(b) (4)	

US3842060

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:35:38

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Zoraida Cruz (b) (4)	21 Oct 2020 19:13:47
	(b) (4)	

US3842060

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:35:38

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '0'	Zoraida Cruz (b) (4)	21 Oct 2020 19:13:47
	(b) (4)	

US3842060

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:35:38

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '0'	Zoraida Cruz (b) (4)	21 Oct 2020 19:13:47
	(b) (4)	

**US3842060**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:35:38**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '0'	Zoraida Cruz (b) (4)	21 Oct 2020 19:13:47
	(b) (4)	

US3842060

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:35:38

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '0'	Zoraida Cruz (b) (4)	21 Oct 2020 19:13:47
	(b) (4)	

US3842060

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:35:38

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '0'	Zoraida Cruz (b) (4)	21 Oct 2020 19:13:47
	(b) (4)	



US3842060

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:35:38

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'I'	Zoraida Cruz (b) (4)	21 Oct 2020 19:13:47
	(b) (4)	

US3842060

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:35:38

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Cuban'	Zoraida Cruz (b) (4)	21 Oct 2020 19:13:47
	(b) (4)	

US3842060

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:35:38

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '0'	Zoraida Cruz (b) (4)	21 Oct 2020 19:13:47
	(b) (4)	

US3842060

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:35:38

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '0'	Zoraida Cruz (b) (4)	21 Oct 2020 19:13:47
	(b) (4)	

US3842060

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:35:38

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '21 Oct 2020'	Zoraida Cruz (b) (4)	21 Oct 2020 19:14:14
	(b) (4)	

US3842060

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:35:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered 'Oct 2020'	System	21 Oct 2020 19:14:14

US3842060

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:35:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered '2020'	System	21 Oct 2020 19:14:14

US3842060

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:35:38

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Amendment 4 (4)'	Zoraida Cruz (b) (4)	21 Oct 2020 19:14:14
	(b) (4)	



US3842060

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:35:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Yes (Y)'	Zoraida Cruz (b) (4)	21 Oct 2020 19:14:14
	(b) (4)	

US3842060

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:35:38

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	21 Oct 2020 19:14:14
	(b) (4)	

US3842060

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:35:38

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	21 Oct 2020 19:14:14
	(b) (4)	

**US3842060**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:35:38**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'No (N)'	Zoraida Cruz (b) (4)	21 Oct 2020 19:14:14
	(b) (4)	

US3842060

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:35:38

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered empty.	RWS_ENDPOINT	21 Oct 2020 16:33:43
	ENDPOINT (b) (4)	

US3842060

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:35:38

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered 'I'	System	21 Oct 2020 19:14:22

US3842060

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 12 Aug 2021 13:35:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Yes (Y)'	Zoraida Cruz (b) (4)	21 Oct 2020 19:14:22
	(b) (4)	

US3842060

Folder: Screening

Form: Medical History Summary

Generated On: 12 Aug 2021 13:35:38

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Yes (Y)'	Zoraida Cruz (b) (4)	21 Oct 2020 19:16:54
	(b) (4)	



US3842060

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:35:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User closed query 'Per DM CLR: Please specify the type of Rhinitis (Allergic or Infective). 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) (4), (b) (6)	25 Jan 2021 12:48:20
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergic rhinitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Jan 2021 22:55:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Jan 2021 22:55:24
Data point term sent to Coder	System	21 Jan 2021 22:54:00
Query 'Per DM CLR: Please specify the type of Rhinitis (Allergic or Infective). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'confirmed with participant during decision visit, and with study nurse. Updated condition for clarification per query ' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	21 Jan 2021 22:53:52
Coding entries removed.	Malithi Desilva (b) (4) (b) (4)	21 Jan 2021 22:53:31
User entered 'SEASONAL RHINITIS (allergic)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	21 Jan 2021 22:53:31
User opened query 'Per DM CLR: Please specify the type of Rhinitis (Allergic or Infective). 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)	15 Jan 2021 08:59:48
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal rhinitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 19:18:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 19:18:34

PRODUCTION RELEASE (v12.003  
EAB) (1725)

368 of 1624

US3842060

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:35:38

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	21 Oct 2020 19:17:42
User entered 'Seasonal Rhinitis'	Zoraida Cruz (b) (4)	21 Oct 2020 19:17:25
	(b) (4)	

US3842060

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:35:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'un UNK 2020'	Zoraida Cruz (b) (4)	21 Oct 2020 19:17:25
	(b) (4)	

US3842060

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:35:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '0'	Zoraida Cruz (b) (4)	21 Oct 2020 19:17:25
	(b) (4)	

US3842060

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:35:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Yes (Y)'	Zoraida Cruz (b) (4)	21 Oct 2020 19:17:25
	(b) (4)	

**US3842060**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:35:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	21 Oct 2020 19:17:25
	(b) (4)	

US3842060

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:35:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '0'	Zoraida Cruz (b) (4)	21 Oct 2020 19:17:25
	(b) (4)	

**US3842060**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:35:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered 'Jan 2020'	System	21 Oct 2020 19:17:25



US3842060

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:35:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered '2020'	System	21 Oct 2020 19:17:25

**US3842060**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:35:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered empty.	System	21 Oct 2020 19:17:25

**US3842060**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:35:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered empty.	System	21 Oct 2020 19:17:25

US3842060

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:35:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
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 protrusion, LLT: Thoracic disc herniation - version MedDRA\\23.0.	Coder Import (b) (4)	22 Oct 2020 06:54:40
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	22 Oct 2020 06:54:40
	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 19:19:46
User entered 'Herniated Disk T10 T11'	Zoraida Cruz (b) (4)	21 Oct 2020 19:19:15
	(b) (4)	

US3842060

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:35:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'un UNK 2020'	Zoraida Cruz (b) (4)	21 Oct 2020 19:19:15
	(b) (4)	

US3842060

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:35:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '0'	Zoraida Cruz (b) (4)	21 Oct 2020 19:19:15
	(b) (4)	

US3842060

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:35:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Yes (Y)'	Zoraida Cruz (b) (4)	21 Oct 2020 19:19:15
	(b) (4)	

US3842060

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:35:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	21 Oct 2020 19:19:15
	(b) (4)	



US3842060

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:35:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '0'	Zoraida Cruz (b) (4)	21 Oct 2020 19:19:15
	(b) (4)	

**US3842060**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:35:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered 'Jan 2020'	System	21 Oct 2020 19:19:15

**US3842060**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:35:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered '2020'	System	21 Oct 2020 19:19:15

US3842060

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:35:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered empty.	System	21 Oct 2020 19:19:15

**US3842060**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:35:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered empty.	System	21 Oct 2020 19:19:15

US3842060

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:35:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Rotator cuff repair, LLT: Rotator cuff repair - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 19:22:36
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 19:22:36
	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 19:21:49
User entered 'Right Rotator Cuff Surgery'	Zoraida Cruz (b) (4)	21 Oct 2020 19:20:49
	(b) (4)	

US3842060

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:35:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'un UNK 2008'	Zoraida Cruz (b) (4)	21 Oct 2020 19:20:49
	(b) (4)	

US3842060

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:35:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '0'	Zoraida Cruz (b) (4)	21 Oct 2020 19:20:49
	(b) (4)	



US3842060

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:35:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'No (N)'	Zoraida Cruz (b) (4)	21 Oct 2020 19:20:49
	(b) (4)	

US3842060

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:35:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'un UNK 2008'	Zoraida Cruz (b) (4)	21 Oct 2020 19:20:49
	(b) (4)	

US3842060

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:35:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '0'	Zoraida Cruz (b) (4)	21 Oct 2020 19:20:49
	(b) (4)	

**US3842060**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:35:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered 'Jan 2008'	System	21 Oct 2020 19:20:49

US3842060

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:35:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered '2008'	System	21 Oct 2020 19:20:49

**US3842060**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:35:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered 'Jan 2008'	System	21 Oct 2020 19:20:49

**US3842060**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:35:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered '2008'	System	21 Oct 2020 19:20:49

US3842060

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:35:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
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 protrusion, LLT: Herniated disc - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 07:13:44
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Nov 2020 07:13:44
	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 19:26:00
User entered 'Chronic Leg Weakness (both) herniated disk'	Zoraida Cruz (b) (4)	21 Oct 2020 19:25:35
	(b) (4)	



US3842060

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:35:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'un UNK 2010'	Zoraida Cruz (b) (4)	21 Oct 2020 19:25:35
	(b) (4)	

US3842060

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:35:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '0'	Zoraida Cruz (b) (4)	21 Oct 2020 19:25:35
	(b) (4)	

US3842060

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:35:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Yes (Y)'	Zoraida Cruz (b) (4)	21 Oct 2020 19:25:35
	(b) (4)	

US3842060

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:35:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	21 Oct 2020 19:25:35
	(b) (4)	

US3842060

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:35:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '0'	Zoraida Cruz (b) (4)	21 Oct 2020 19:25:35
	(b) (4)	

**US3842060**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:35:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered 'Jan 2010'	System	21 Oct 2020 19:25:35

**US3842060**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:35:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered '2010'	System	21 Oct 2020 19:25:35

US3842060

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:35:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered empty.	System	21 Oct 2020 19:25:35



**US3842060**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:35:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered empty.	System	21 Oct 2020 19:25:35

US3842060

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:35:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:56:39
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Peripheral sensory neuropathy, LLT: Peripheral sensory neuropathy - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 08:56:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 08:56:18
Data point term sent to Coder	System	10 Mar 2021 21:23:27
User closed query 'CDM-Coding: Please clarify this clinical event with more details if it is Sensory neuropathy or Motor neuropathy and amend /update the term accordingly in the diagnosis field to enable coding. Thank you.' (Site from System).	System	10 Mar 2021 21:22:49
Query 'CDM-Coding: Please clarify this clinical event with more details if it is Sensory neuropathy or Motor neuropathy and amend /update the term accordingly in the diagnosis field to enable coding. Thank you.' answered with 'Per query, information provided' (Site from System).	Mario Portilla (b) (4)	10 Mar 2021 21:22:49
Data point term sent to Coder	System	10 Mar 2021 21:22:25
User entered 'NEUROPATHY, RIGHT SIDE OF FACE (Sensory)' reason for change: Data Entry Error	Mario Portilla (b) (4)	10 Mar 2021 21:22:15
User opened query 'CDM-Coding: Please clarify this clinical event with more details if it is Sensory neuropathy or Motor neuropathy and amend /update the term accordingly in the diagnosis field to enable coding. Thank you.' (Site from System).	Coder Import (b) (4)	10 Mar 2021 11:17:50
Data point term sent to Coder	System	09 Mar 2021 22:14:18
User entered 'Neuropathy, right side of face'	Mario Portilla (b) (4)	09 Mar 2021 22:14:11

US3842060

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:35:38

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:56:39
	(b) (4)	
User entered 'UN UNK 2010' reason for change: Data Entry Error	Mario Portilla (b) (4)	09 Mar 2021 22:16:09
	(b) (4)	
User entered 'un UNK 2019'	Mario Portilla (b) (4)	09 Mar 2021 22:14:11
	(b) (4)	

US3842060

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:35:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:56:39
	(b) (4)	
User entered '0'	Mario Portilla (b) (4)	09 Mar 2021 22:14:11
	(b) (4)	

US3842060

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:35:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:56:39
	(b) (4)	
User entered 'Yes (Y)'	Mario Portilla (b) (4)	09 Mar 2021 22:14:11
	(b) (4)	

US3842060

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:35:38

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:56:39
	(b) (4)	
User entered empty.	Mario Portilla (b) (4)	09 Mar 2021 22:14:11
	(b) (4)	

US3842060

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:35:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:56:39
	(b) (4)	
User entered '0'	Mario Portilla (b) (4)	09 Mar 2021 22:14:11
	(b) (4)	

**US3842060**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:35:38**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered 'Jan 2010'	System	09 Mar 2021 22:16:09
User entered 'Jan 2019'	System	09 Mar 2021 22:14:11



US3842060

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:35:38

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered '2010'	System	09 Mar 2021 22:16:09
User entered '2019'	System	09 Mar 2021 22:14:11

US3842060

Folder: Screening

Form: Medical History (5)

Generated On: 12 Aug 2021 13:35:38

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered empty.	System	09 Mar 2021 22:14:11

**US3842060**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 12 Aug 2021 13:35:38**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered empty.	System	09 Mar 2021 22:14:11

US3842060

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Yes (Y)'	Zoraida Cruz (b) (4)	21 Oct 2020 19:28:23
	(b) (4)	

US3842060

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	21 Oct 2020 19:29:11
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	21 Oct 2020 19:29:11
User closed query 'The Assessment Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	21 Oct 2020 19:29:11
User entered '21 Oct 2020' reason for change: Data Entry Error	Malithi Desilva (b) (4)	21 Oct 2020 19:29:11
	(b) (4)	
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	21 Oct 2020 19:28:23
User opened query 'The Assessment Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	21 Oct 2020 19:28:23
User entered '20 Oct 2020'	Zoraida Cruz (b) (4)	21 Oct 2020 19:28:23
	(b) (4)	

US3842060

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '13:09'	Zoraida Cruz (b) (4)	21 Oct 2020 19:28:23
	(b) (4)	

US3842060

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered '21 Oct 2020 13:09'	System	21 Oct 2020 19:29:11
User entered '20 Oct 2020 13:09'	System	21 Oct 2020 19:28:23

US3842060

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '174.5' cm	Zoraida Cruz (b) (4)	21 Oct 2020 19:28:23
	(b) (4)	
DataPoint set to visible.	System	21 Oct 2020 19:14:22



US3842060

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '88.3' kg	Zoraida Cruz (b) (4)	21 Oct 2020 19:28:23
	(b) (4)	
DataPoint set to visible.	System	21 Oct 2020 19:14:22

US3842060

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered '28.99812'	System	21 Oct 2020 19:28:23
DataPoint set to visible.	System	21 Oct 2020 19:14:22

US3842060

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered 'kg/m2'	System	21 Oct 2020 19:28:23
DataPoint set to visible.	System	21 Oct 2020 19:14:22

US3842060

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered missing code ND - Not Done.	Zoraida Cruz (b) (4)	21 Oct 2020 19:28:23
	(b) (4)	

US3842060

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	21 Oct 2020 19:28:23
	(b) (4)	

US3842060

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	21 Oct 2020 19:28:23
	(b) (4)	

US3842060

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered missing code ND - Not Done.	Zoraida Cruz (b) (4)	21 Oct 2020 19:28:23
	(b) (4)	

US3842060

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered 'bpm'	System	21 Oct 2020 19:28:23



US3842060

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered missing code ND - Not Done.	Zoraida Cruz (b) (4)	21 Oct 2020 19:28:23
	(b) (4)	

US3842060

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered 'breaths/min'	System	21 Oct 2020 19:28:23

US3842060

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered missing code ND - Not Done.	Zoraida Cruz (b) (4)	21 Oct 2020 19:28:23
	(b) (4)	

US3842060

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered 'mmHg'	System	21 Oct 2020 19:28:23

US3842060

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered missing code ND - Not Done.	Zoraida Cruz (b) (4)	21 Oct 2020 19:28:23
	(b) (4)	

US3842060

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered 'mmHg'	System	21 Oct 2020 19:28:23

US3842060

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05

US3842060

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05



US3842060

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:35:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Yes (Y)'	Zoraida Cruz (b) (4)	21 Oct 2020 19:28:52
	(b) (4)	

US3842060

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:35:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	21 Oct 2020 19:29:00
User closed query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	21 Oct 2020 19:29:00
User entered '21 Oct 2020' reason for change: Data Entry Error	Zoraida Cruz (b) (4)	21 Oct 2020 19:29:00
	(b) (4)	
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	21 Oct 2020 19:28:52
User opened query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	21 Oct 2020 19:28:52
User entered '20 Oct 2020'	Zoraida Cruz (b) (4)	21 Oct 2020 19:28:52
	(b) (4)	

US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:35:38

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 19:03:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 19:03:37
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	26 Oct 2020 19:03:37
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 19:31:56
User entered empty.	Zoraida Cruz (b) (4)	21 Oct 2020 19:31:56
	(b) (4)	

US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:35:38

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 19:03:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 19:03:37
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	26 Oct 2020 19:03:37
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 19:31:56
User entered empty.	Zoraida Cruz (b) (4)	21 Oct 2020 19:31:56
	(b) (4)	

US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:35:38

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 19:03:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 19:03:37
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	26 Oct 2020 19:03:37
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 19:31:56
User entered empty.	Zoraida Cruz (b) (4)	21 Oct 2020 19:31:56
	(b) (4)	

US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:35:38

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 19:03:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 19:03:37
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	26 Oct 2020 19:03:37
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 19:31:56
User entered empty.	Zoraida Cruz (b) (4)	21 Oct 2020 19:31:56
	(b) (4)	

US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:35:38

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 19:03:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 19:03:37
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	26 Oct 2020 19:03:37
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 19:31:56
User entered empty.	Zoraida Cruz (b) (4)	21 Oct 2020 19:31:56
	(b) (4)	

US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:35:38

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 19:03:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 19:03:37
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	26 Oct 2020 19:03:37
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 19:31:56
User entered empty.	Zoraida Cruz (b) (4)	21 Oct 2020 19:31:56
	(b) (4)	



US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:35:38

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 19:03:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 19:03:37
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	26 Oct 2020 19:03:37
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 19:31:56
User entered empty.	Zoraida Cruz (b) (4)	21 Oct 2020 19:31:56
	(b) (4)	

US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:35:38

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 19:03:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 19:03:37
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	26 Oct 2020 19:03:37
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 19:31:56
User entered empty.	Zoraida Cruz (b) (4)	21 Oct 2020 19:31:56
	(b) (4)	

US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:35:38

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 19:03:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 19:03:37
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	26 Oct 2020 19:03:37
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 19:31:56
User entered empty.	Zoraida Cruz (b) (4)	21 Oct 2020 19:31:56
	(b) (4)	

US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:35:38

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 19:03:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 19:03:37
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	26 Oct 2020 19:03:37
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 19:31:56
User entered empty.	Zoraida Cruz (b) (4)	21 Oct 2020 19:31:56
	(b) (4)	

US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:35:38

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 19:03:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 19:03:37
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	26 Oct 2020 19:03:37
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 19:31:56
User entered empty.	Zoraida Cruz (b) (4)	21 Oct 2020 19:31:56
	(b) (4)	

US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:35:38

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Yes (Y)'	Zoraida Cruz (b) (4)	21 Oct 2020 19:31:56
	(b) (4)	

US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:35:38

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Corrections'	Zoraida Cruz (b) (4)	21 Oct 2020 19:31:56
	(b) (4)	

US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:35:38

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '0'	Zoraida Cruz (b) (4)	21 Oct 2020 19:31:56
	(b) (4)	



US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:35:38

**Resides in Nursing Home or Assisted Living Facility**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '0'	Zoraida Cruz (b) (4)	21 Oct 2020 19:31:56
	(b) (4)	

US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:35:38

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '0'	Zoraida Cruz (b) (4)	21 Oct 2020 19:31:56
	(b) (4)	

US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:35:38

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '0'	Zoraida Cruz (b) (4)	21 Oct 2020 19:31:56
	(b) (4)	

US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:35:38

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '0'	Zoraida Cruz (b) (4)	21 Oct 2020 19:31:56
	(b) (4)	

US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:35:38

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'I'	Zoraida Cruz (b) (4)	21 Oct 2020 19:31:56
	(b) (4)	

US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:35:38

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '0'	Zoraida Cruz (b) (4)	21 Oct 2020 19:31:56
	(b) (4)	

US3842060

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:35:38

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	21 Oct 2020 19:31:56
	(b) (4)	

US3842060

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:35:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Yes (Y)'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:32:11



**US3842060**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:35:38**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '21 Oct 2020'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:32:11

US3842060

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:35:38

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Clinic (Clinic)'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:32:11

**US3842060**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:35:38**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered 'VISIT1'	System	21 Oct 2020 19:32:11

US3842060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:35:38

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '21 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Oct 2020 17:43:39

US3842060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:35:38

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '117719'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Oct 2020 17:43:39

US3842060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:35:38

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Oct 2020 17:43:39

US3842060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:35:38

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Oct 2020 19:02:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 19:02:20
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	26 Oct 2020 19:02:20
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Oct 2020 19:32:29
User entered empty.	System	21 Oct 2020 19:32:29
	Zoraida Cruz (b) (4)	21 Oct 2020 19:32:29
	(b) (4)	

US3842060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:35:38

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Oct 2020 19:02:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 19:02:20
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	26 Oct 2020 19:02:20
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Oct 2020 19:32:29
User entered empty.	System	21 Oct 2020 19:32:29
	Zoraida Cruz (b) (4)	21 Oct 2020 19:32:29
	(b) (4)	



US3842060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:35:38

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Oct 2020 19:02:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 19:02:20
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	26 Oct 2020 19:02:20
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Oct 2020 19:32:29
User entered empty.	System	21 Oct 2020 19:32:29
	Zoraida Cruz (b) (4)	21 Oct 2020 19:32:29
	(b) (4)	

US3842060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:35:38

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Oct 2020 19:02:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 19:02:20
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	26 Oct 2020 19:02:20
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Oct 2020 19:32:29
User entered empty.	System	21 Oct 2020 19:32:29
	Zoraida Cruz (b) (4)	21 Oct 2020 19:32:29
	(b) (4)	

US3842060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:35:38

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Oct 2020 19:02:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 19:02:20
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	26 Oct 2020 19:02:20
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Oct 2020 19:32:29
User entered empty.	System	21 Oct 2020 19:32:29
	Zoraida Cruz (b) (4)	21 Oct 2020 19:32:29
	(b) (4)	

US3842060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:35:38

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Oct 2020 19:02:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 19:02:20
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	26 Oct 2020 19:02:20
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Oct 2020 19:32:29
User entered empty.	System	21 Oct 2020 19:32:29
DataPoint set to visible.	Zoraida Cruz (b) (4)	21 Oct 2020 19:32:29
	(b) (4)	21 Oct 2020 19:14:14

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:35:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:35:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:35:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:35:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29



US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User accepted default value 'Pre-Dose (PREDOSE)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Yes (Y)'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '21 Oct 2020'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '13:09'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered '21 Oct 2020 13:09'	System	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '98.2' F	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Oral (Oral)'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29



US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '72'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered 'bpm'	System	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '16'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered 'breaths/min'	System	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '139'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered 'mmHg'	System	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '87'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered 'mmHg'	System	21 Oct 2020 20:49:29



US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:35:38

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:35:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User accepted default value 'Post-Dose (POSTDOSE)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Yes (Y)'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '21 Oct 2020'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '16:11'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered '21 Oct 2020 16:11'	System	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '98.0' F	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29



US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Oral (Oral)'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '65'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered 'bpm'	System	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '16'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered 'breaths/min'	System	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '133'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered 'mmHg'	System	21 Oct 2020 20:49:29



US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '85'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered 'mmHg'	System	21 Oct 2020 20:49:29

US3842060

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:35:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'No (N)'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:49:01

US3842060

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:35:38

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:49:01

US3842060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:35:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Yes (Y)'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:49:42

US3842060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:35:38

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:49:42

US3842060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:35:38

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:49:42

US3842060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:35:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered 'MRNA-1273 OR PLACEBO'	System	21 Oct 2020 19:49:42



US3842060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:35:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '21 Oct 2020'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:49:42

US3842060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:35:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '15:40'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:49:42

US3842060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:35:38

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered '21 Oct 2020 15:40'	System	21 Oct 2020 19:49:42

US3842060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:35:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Left Arm (LEFT ARM)'	Zoraida Cruz (b) (4)	21 Oct 2020 19:49:42

US3842060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:35:38

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered 'ONCE'	System	21 Oct 2020 19:49:42

US3842060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:35:38

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered 'INTRAMUSCULAR'	System	21 Oct 2020 19:49:42

US3842060

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:35:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Yes (Y)'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:50:37

US3842060

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:35:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	21 Oct 2020 19:50:56
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).	System	21 Oct 2020 19:50:56
User closed query 'The Collection Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	21 Oct 2020 19:50:56
User closed query 'The Collection Date is prior to the System Screening Visit Date. Please review and reconcile.' (Site from System).	System	21 Oct 2020 19:50:56
User entered '21 Oct 2020' reason for change: Data Entry Error	Zoraida Cruz (b) (4)	21 Oct 2020 19:50:56
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	21 Oct 2020 19:50:37
User opened query 'The Collection Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	21 Oct 2020 19:50:37
User opened query 'The Collection Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	21 Oct 2020 19:50:37
User entered '20 Oct 2020'	Zoraida Cruz (b) (4)	21 Oct 2020 19:50:37



US3842060

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:35:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '13:52'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:50:37

US3842060

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:35:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered '21 Oct 2020 13:52'	System	21 Oct 2020 19:50:56
User entered '20 Oct 2020 13:52'	System	21 Oct 2020 19:50:37

US3842060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:35:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '21 Oct 2020'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:51:30

US3842060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:35:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:51:30

US3842060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:35:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Yes (Y)'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:51:30

US3842060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:35:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '13:58'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:51:30

US3842060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:35:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered '21 Oct 2020 13:58'	System	21 Oct 2020 19:51:30

US3842060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:35:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:51:30



US3842060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:35:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'No (N)'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:51:30

US3842060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:35:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:51:30

**US3842060**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 13:35:38**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered empty.	System	21 Oct 2020 19:51:30

US3842060

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:35:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Yes (Y)'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:51:46

**US3842060**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:35:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered 'I'	System	21 Oct 2020 19:51:46

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:35:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T16:16:05', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '4dd00882-fee8-4425-942a-acb60eccde5f' User entered 'Yes (Y)'	System	21 Oct 2020 20:16:30
	System	21 Oct 2020 20:16:30

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:35:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T16:16:14', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '4dd00882-fee8-4425-942a-acb60eccde5f' User entered '98.0'	System	21 Oct 2020 20:16:30
	System	21 Oct 2020 20:16:30



US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:35:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T16:16:22', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '4dd00882-fee8-4425-942a-acb60eccde5f' User entered 'No (N)'	System	21 Oct 2020 20:16:30
	System	21 Oct 2020 20:16:30

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:35:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T16:16:26', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '4dd00882-fee8-4425-942a-acb60eccde5f' User entered '21 Oct 2020 16:16'	System	21 Oct 2020 20:16:30
	System	21 Oct 2020 20:16:30

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:35:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '21 Oct 2020 16:00'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:35:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '21 Oct 2020 18:30'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 1, after vaccination (at home)'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:35:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T20:14:54', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f0c50f81-4b15-4fe5-9003-202d092432dc' User entered 'Yes (Y)'	System	22 Oct 2020 00:17:30
	System	22 Oct 2020 00:17:30

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:35:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T20:17:17', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f0c50f81-4b15-4fe5-9003-202d092432dc' User entered '97.2'	System	22 Oct 2020 00:17:30
	System	22 Oct 2020 00:17:30

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:35:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T20:17:23', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f0c50f81-4b15-4fe5-9003-202d092432dc'	System	22 Oct 2020 00:17:30
User entered 'No (N)'	System	22 Oct 2020 00:17:30



US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:35:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T20:17:27', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f0c50f81-4b15-4fe5-9003-202d092432dc' User entered '21 Oct 2020 20:17'	System	22 Oct 2020 00:17:30
	System	22 Oct 2020 00:17:30

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:35:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '21 Oct 2020 19:25'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:35:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '22 Oct 2020 11:59'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 2'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:35:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-22T17:11:54', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '7195ebf8-38d9-4f04-9181-ec0115e56497'	System	22 Oct 2020 21:12:08
User entered 'Yes (Y)'	System	22 Oct 2020 21:12:08

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:35:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-22T17:12:00', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '7195ebf8-38d9-4f04-9181-ec0115e56497' User entered '97.0'	System	22 Oct 2020 21:12:08
	System	22 Oct 2020 21:12:08

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:35:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-22T17:12:03', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '7195ebf8-38d9-4f04-9181-ec0115e56497'	System	22 Oct 2020 21:12:08
User entered 'No (N)'	System	22 Oct 2020 21:12:08

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:35:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-22T17:12:06', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '7195ebf8-38d9-4f04-9181-ec0115e56497' User entered '22 Oct 2020 17:12'	System	22 Oct 2020 21:12:08
	System	22 Oct 2020 21:12:08



US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:35:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:35:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 3'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:35:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-23T12:02:33', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'd23d8533-cdef-437f-a1d3-a46e752d6300' User entered 'Yes (Y)'	System	23 Oct 2020 16:05:15
	System	23 Oct 2020 16:05:15

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:35:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-23T12:03:01', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'd23d8533-cdef-437f-a1d3-a46e752d6300' User entered '96.3'	System	23 Oct 2020 16:05:15
	System	23 Oct 2020 16:05:15

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:35:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-23T12:03:08', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'd23d8533-cdef-437f-a1d3-a46e752d6300'	System	23 Oct 2020 16:05:15
User entered 'No (N)'	System	23 Oct 2020 16:05:15

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:35:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-23T12:03:11', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'd23d8533-cdef-437f-a1d3-a46e752d6300' User entered '23 Oct 2020 12:03'	System	23 Oct 2020 16:05:15
	System	23 Oct 2020 16:05:15

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:35:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 19:49:42



US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:35:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 4'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:35:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-24T13:01:09', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'e8243abb-b900-48e5-a253-802e5db3bf58' User entered 'Yes (Y)'	System	24 Oct 2020 17:01:28
	System	24 Oct 2020 17:01:28

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:35:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-24T13:01:18', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'e8243abb-b900-48e5-a253-802e5db3bf58' User entered '96.9'	System	24 Oct 2020 17:01:28
	System	24 Oct 2020 17:01:28

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:35:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-24T13:01:23', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'e8243abb-b900-48e5-a253-802e5db3bf58'	System	24 Oct 2020 17:01:28
User entered 'No (N)'	System	24 Oct 2020 17:01:28

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:35:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-24T13:01:25', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'e8243abb-b900-48e5-a253-802e5db3bf58' User entered '24 Oct 2020 13:01'	System	24 Oct 2020 17:01:28
	System	24 Oct 2020 17:01:28

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:35:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '24 Oct 2020 12:00'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:35:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '25 Oct 2020 11:59'	System	21 Oct 2020 19:49:42



US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 5'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:35:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-25T13:10:17', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '4ac236f2-a1ab-4384-9af0-461e4fadec39' User entered 'Yes (Y)'	System	25 Oct 2020 17:11:46
	System	25 Oct 2020 17:11:46

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:35:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-25T13:11:35', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '4ac236f2-a1ab-4384-9af0-461e4fadec39' User entered '96.2'	System	25 Oct 2020 17:11:46
	System	25 Oct 2020 17:11:46

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:35:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-25T13:11:41', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '4ac236f2-a1ab-4384-9af0-461e4fadec39'	System	25 Oct 2020 17:11:46
User entered 'No (N)'	System	25 Oct 2020 17:11:46

**US3842060**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 12 Aug 2021 13:35:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-25T13:11:44', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '4ac236f2-a1ab-4384-9af0-461e4fadec39' User entered '25 Oct 2020 13:11'	System	25 Oct 2020 17:11:46
	System	25 Oct 2020 17:11:46

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:35:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '25 Oct 2020 12:00'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:35:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '26 Oct 2020 11:59'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 6'	System	21 Oct 2020 19:49:42



US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:35:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-26T16:38:38', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'e6a2cfca-8cc9-41e0-8dcb-044d70608638' User entered 'Yes (Y)'	System	26 Oct 2020 20:38:59
	System	26 Oct 2020 20:38:59

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:35:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-26T16:38:44', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'e6a2cfca-8cc9-41e0-8dcb-044d70608638' User entered '95.9'	System	26 Oct 2020 20:38:59
	System	26 Oct 2020 20:38:59

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:35:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-26T16:38:50', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'e6a2cfca-8cc9-41e0-8dcb-044d70608638' User entered 'No (N)'	System	26 Oct 2020 20:38:59
	System	26 Oct 2020 20:38:59

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:35:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-26T16:38:53', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'e6a2cfca-8cc9-41e0-8dcb-044d70608638' User entered '26 Oct 2020 16:38'	System	26 Oct 2020 20:38:59
	System	26 Oct 2020 20:38:59

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:35:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '26 Oct 2020 12:00'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:35:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '27 Oct 2020 11:59'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 7'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:35:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-27T19:00:22', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f05177ad-2a33-4a18-9a55-cdd223759c54' User entered 'Yes (Y)'	System	27 Oct 2020 23:00:56
	System	27 Oct 2020 23:00:56



US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:35:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-27T19:00:42', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f05177ad-2a33-4a18-9a55-cdd223759c54' User entered '97.0'	System	27 Oct 2020 23:00:56
	System	27 Oct 2020 23:00:56

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:35:38

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-27T19:00:49', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f05177ad-2a33-4a18-9a55-cdd223759c54' User entered 'No (N)'	System	27 Oct 2020 23:00:56
	System	27 Oct 2020 23:00:56

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:35:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-27T19:00:52', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f05177ad-2a33-4a18-9a55-cdd223759c54' User entered '27 Oct 2020 19:00'	System	27 Oct 2020 23:00:56
	System	27 Oct 2020 23:00:56

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:35:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '27 Oct 2020 12:00'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:35:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '28 Oct 2020 11:59'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:35:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T16:17:02', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'fb6310eb-996a-49c2-a859-fe42b92db1f3'	System	21 Oct 2020 20:20:08
User entered 'None (1)'	System	21 Oct 2020 20:20:08

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:35:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T16:19:37', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'fb6310eb-996a-49c2-a859-fe42b92db1f3'	System	21 Oct 2020 20:20:08
User entered 'No (N)'	System	21 Oct 2020 20:20:08



US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:35:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T16:19:42', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'fb6310eb-996a-49c2-a859-fe42b92db1f3'	System	21 Oct 2020 20:20:08
User entered 'No (N)'	System	21 Oct 2020 20:20:08

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:35:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T16:19:58', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'fb6310eb-996a-49c2-a859-fe42b92db1f3'	System	21 Oct 2020 20:20:08
User entered 'None (1)'	System	21 Oct 2020 20:20:08

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:35:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T16:20:06', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'fb6310eb-996a-49c2-a859-fe42b92db1f3'	System	21 Oct 2020 20:20:08
User entered '21 Oct 2020 16:20'	System	21 Oct 2020 20:20:08

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:35:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '21 Oct 2020 16:00'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:35:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '21 Oct 2020 18:30'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 1, after vaccination (at home)'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:35:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T20:17:40', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f3f3bdb1-f9c0-4f9f-9cab-42aa08591891'	System	22 Oct 2020 00:18:52
User entered 'None (1)'	System	22 Oct 2020 00:18:52

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:35:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T20:18:02', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f3f3bdb1-f9c0-4f9f-9cab-42aa08591891' User entered 'No (N)'	System	22 Oct 2020 00:18:52
	System	22 Oct 2020 00:18:52



US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:35:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T20:18:21', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f3f3bdb1-f9c0-4f9f-9cab-42aa08591891' User entered 'No (N)'	System	22 Oct 2020 00:18:52
	System	22 Oct 2020 00:18:52

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:35:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T20:18:42', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f3f3bdb1-f9c0-4f9f-9cab-42aa08591891'	System	22 Oct 2020 00:18:52
User entered 'None (1)'	System	22 Oct 2020 00:18:52

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:35:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T20:18:51', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f3f3bdb1-f9c0-4f9f-9cab-42aa08591891' User entered '21 Oct 2020 20:18'	System	22 Oct 2020 00:18:52
	System	22 Oct 2020 00:18:52

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:35:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '21 Oct 2020 19:25'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:35:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '22 Oct 2020 11:59'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 2'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:35:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-22T17:12:12', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f4b8c8ec-d6ce-4b39-a8b0-f5b8fd8df1de' User entered 'None (1)'	System	22 Oct 2020 21:12:38
	System	22 Oct 2020 21:12:38

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:35:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-22T17:12:16', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f4b8c8ec-d6ce-4b39-a8b0-f5b8fd8df1de' User entered 'No (N)'	System	22 Oct 2020 21:12:38
	System	22 Oct 2020 21:12:38



US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:35:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-22T17:12:20', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f4b8c8ec-d6ce-4b39-a8b0-f5b8fd8df1de' User entered 'No (N)'	System	22 Oct 2020 21:12:38
	System	22 Oct 2020 21:12:38

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:35:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-22T17:12:29', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f4b8c8ec-d6ce-4b39-a8b0-f5b8fd8df1de' User entered 'None (1)'	System	22 Oct 2020 21:12:38
	System	22 Oct 2020 21:12:38

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:35:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-22T17:12:33', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f4b8c8ec-d6ce-4b39-a8b0-f5b8fd8df1de' User entered '22 Oct 2020 17:12'	System	22 Oct 2020 21:12:38
	System	22 Oct 2020 21:12:38

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:35:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:35:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 3'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:35:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-23T12:03:28', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '8e0adcc5-1985-4172-b8bb-82d0f0639a71'	System	23 Oct 2020 16:06:05
User entered 'None (1)'	System	23 Oct 2020 16:06:05

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:35:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-23T12:03:32', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '8e0adcc5-1985-4172-b8bb-82d0f0639a71' User entered 'No (N)'	System	23 Oct 2020 16:06:05
	System	23 Oct 2020 16:06:05



US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:35:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-23T12:03:38', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '8e0adcc5-1985-4172-b8bb-82d0f0639a71' User entered 'No (N)'	System	23 Oct 2020 16:06:05
	System	23 Oct 2020 16:06:05

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:35:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-23T12:03:50', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '8e0adcc5-1985-4172-b8bb-82d0f0639a71'	System	23 Oct 2020 16:06:05
User entered 'None (1)'	System	23 Oct 2020 16:06:05

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:35:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-23T12:03:53', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '8e0adcc5-1985-4172-b8bb-82d0f0639a71' User entered '23 Oct 2020 12:03'	System	23 Oct 2020 16:06:05
	System	23 Oct 2020 16:06:05

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:35:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:35:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 4'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:35:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-24T13:01:33', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '5b00e166-f378-43db-b725-3a9ee6703b64' User entered 'None (1)'	System	24 Oct 2020 17:01:55
	System	24 Oct 2020 17:01:55

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:35:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-24T13:01:37', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '5b00e166-f378-43db-b725-3a9ee6703b64' User entered 'No (N)'	System	24 Oct 2020 17:01:55
	System	24 Oct 2020 17:01:55



US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:35:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-24T13:01:41', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '5b00e166-f378-43db-b725-3a9ee6703b64' User entered 'No (N)'	System	24 Oct 2020 17:01:55
	System	24 Oct 2020 17:01:55

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:35:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-24T13:01:49', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '5b00e166-f378-43db-b725-3a9ee6703b64' User entered 'None (1)'	System	24 Oct 2020 17:01:55
	System	24 Oct 2020 17:01:55

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:35:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-24T13:01:53', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '5b00e166-f378-43db-b725-3a9ee6703b64' User entered '24 Oct 2020 13:01'	System	24 Oct 2020 17:01:55
	System	24 Oct 2020 17:01:55

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:35:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '24 Oct 2020 12:00'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:35:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '25 Oct 2020 11:59'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 5'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:35:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-25T13:11:49', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f697aef2-220e-469f-b89a-c62ae3183a3c'	System	25 Oct 2020 17:12:15
User entered 'None (1)'	System	25 Oct 2020 17:12:15

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:35:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-25T13:11:52', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f697aef2-220e-469f-b89a-c62ae3183a3c' User entered 'No (N)'	System	25 Oct 2020 17:12:15
	System	25 Oct 2020 17:12:15



US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:35:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-25T13:11:55', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f697aef2-220e-469f-b89a-c62ae3183a3c' User entered 'No (N)'	System	25 Oct 2020 17:12:15
	System	25 Oct 2020 17:12:15

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:35:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-25T13:12:07', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f697aef2-220e-469f-b89a-c62ae3183a3c'	System	25 Oct 2020 17:12:15
User entered 'None (1)'	System	25 Oct 2020 17:12:15

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:35:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-25T13:12:10', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'f697aef2-220e-469f-b89a-c62ae3183a3c' User entered '25 Oct 2020 13:12'	System	25 Oct 2020 17:12:15
	System	25 Oct 2020 17:12:15

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:35:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '25 Oct 2020 12:00'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:35:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '26 Oct 2020 11:59'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 6'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:35:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-26T16:38:58', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '7193c7e7-c504-486e-bfab-af082d7586f8'	System	26 Oct 2020 20:39:15
User entered 'None (1)'	System	26 Oct 2020 20:39:15

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:35:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-26T16:39:04', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '7193c7e7-c504-486e-bfab-af082d7586f8' User entered 'No (N)'	System	26 Oct 2020 20:39:15
	System	26 Oct 2020 20:39:15



US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:35:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-26T16:39:08', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '7193c7e7-c504-486e-bfab-af082d7586f8' User entered 'No (N)'	System	26 Oct 2020 20:39:15
	System	26 Oct 2020 20:39:15

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:35:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-26T16:39:10', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '7193c7e7-c504-486e-bfab-af082d7586f8'	System	26 Oct 2020 20:39:15
User entered 'None (1)'	System	26 Oct 2020 20:39:15

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:35:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-26T16:39:13', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '7193c7e7-c504-486e-bfab-af082d7586f8' User entered '26 Oct 2020 16:39'	System	26 Oct 2020 20:39:15
	System	26 Oct 2020 20:39:15

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:35:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '26 Oct 2020 12:00'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:35:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '27 Oct 2020 11:59'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 7'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:35:38

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-27T19:00:55', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'bb15805a-08a9-4a65-90ac-a1ed352f9d0f'	System	27 Oct 2020 23:01:22
User entered 'None (1)'	System	27 Oct 2020 23:01:22

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:35:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-27T19:01:09', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'bb15805a-08a9-4a65-90ac-a1ed352f9d0f' User entered 'No (N)'	System	27 Oct 2020 23:01:22
	System	27 Oct 2020 23:01:22



US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:35:38

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-27T19:01:15', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'bb15805a-08a9-4a65-90ac-a1ed352f9d0f' User entered 'No (N)'	System	27 Oct 2020 23:01:22
	System	27 Oct 2020 23:01:22

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:35:38

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-27T19:01:18', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'bb15805a-08a9-4a65-90ac-a1ed352f9d0f' User entered 'None (1)'	System	27 Oct 2020 23:01:22
	System	27 Oct 2020 23:01:22

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:35:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-27T19:01:20', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'bb15805a-08a9-4a65-90ac-a1ed352f9d0f' User entered '27 Oct 2020 19:01'	System	27 Oct 2020 23:01:22
	System	27 Oct 2020 23:01:22

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:35:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '27 Oct 2020 12:00'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:35:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '28 Oct 2020 11:59'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:35:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T16:20:17', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'c8633421-fc51-46af-a62b-b333255a80c8' User entered 'None (0)'	System	21 Oct 2020 20:21:10
	System	21 Oct 2020 20:21:10

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:35:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T16:20:24', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'c8633421-fc51-46af-a62b-b333255a80c8' User entered 'None (0)'	System	21 Oct 2020 20:21:10
	System	21 Oct 2020 20:21:10



US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:35:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T16:20:33', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'c8633421-fc51-46af-a62b-b333255a80c8' User entered 'None (0)'	System	21 Oct 2020 20:21:10
	System	21 Oct 2020 20:21:10

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:35:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T16:20:41', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'c8633421-fc51-46af-a62b-b333255a80c8' User entered 'None (0)'	System	21 Oct 2020 20:21:10
	System	21 Oct 2020 20:21:10

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:35:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T16:20:45', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'c8633421-fc51-46af-a62b-b333255a80c8' User entered 'None (0)'	System	21 Oct 2020 20:21:10
	System	21 Oct 2020 20:21:10

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:35:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T16:20:51', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'c8633421-fc51-46af-a62b-b333255a80c8' User entered 'None (0)'	System	21 Oct 2020 20:21:10
	System	21 Oct 2020 20:21:10

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:35:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T16:21:02', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'c8633421-fc51-46af-a62b-b333255a80c8' User entered 'No (N)'	System	21 Oct 2020 20:21:10
	System	21 Oct 2020 20:21:10

**US3842060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:35:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T16:21:09', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'c8633421-fc51-46af-a62b-b333255a80c8' User entered '21 Oct 2020 16:21'	System	21 Oct 2020 20:21:10
	System	21 Oct 2020 20:21:10

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:35:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '21 Oct 2020 16:00'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:35:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '21 Oct 2020 18:30'	System	21 Oct 2020 19:49:42



US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 1, after vaccination (at home)'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:35:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T20:19:02', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '90ee672b-956e-4c33-98d2-bfb1ca7363fd' User entered 'None (0)'	System	22 Oct 2020 00:19:40
	System	22 Oct 2020 00:19:40

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:35:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T20:19:06', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '90ee672b-956e-4c33-98d2-bfb1ca7363fd' User entered 'None (0)'	System	22 Oct 2020 00:19:40
	System	22 Oct 2020 00:19:40

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:35:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T20:19:10', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '90ee672b-956e-4c33-98d2-bfb1ca7363fd' User entered 'None (0)'	System	22 Oct 2020 00:19:40
	System	22 Oct 2020 00:19:40

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:35:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T20:19:14', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '90ee672b-956e-4c33-98d2-bfb1ca7363fd' User entered 'None (0)'	System	22 Oct 2020 00:19:40
	System	22 Oct 2020 00:19:40

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:35:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T20:19:17', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '90ee672b-956e-4c33-98d2-bfb1ca7363fd' User entered 'None (0)'	System	22 Oct 2020 00:19:40
	System	22 Oct 2020 00:19:40

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:35:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T20:19:20', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '90ee672b-956e-4c33-98d2-bfb1ca7363fd' User entered 'None (0)'	System	22 Oct 2020 00:19:40
	System	22 Oct 2020 00:19:40

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:35:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T20:19:32', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '90ee672b-956e-4c33-98d2-bfb1ca7363fd' User entered 'No (N)'	System	22 Oct 2020 00:19:40
	System	22 Oct 2020 00:19:40



US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:35:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-21T20:19:38', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '90ee672b-956e-4c33-98d2-bfb1ca7363fd' User entered '21 Oct 2020 20:19'	System	22 Oct 2020 00:19:40
	System	22 Oct 2020 00:19:40

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:35:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '21 Oct 2020 19:25'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:35:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '22 Oct 2020 11:59'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 2'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:35:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-22T17:12:40', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '40b51bdf-2d30-42f1-9bcc-f283c8d987d4' User entered 'None (0)'	System	22 Oct 2020 21:13:14
	System	22 Oct 2020 21:13:14

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:35:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-22T17:12:46', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '40b51bdf-2d30-42f1-9bcc-f283c8d987d4' User entered 'None (0)'	System	22 Oct 2020 21:13:14
	System	22 Oct 2020 21:13:14

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:35:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-22T17:12:51', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '40b51bdf-2d30-42f1-9bcc-f283c8d987d4' User entered 'None (0)'	System	22 Oct 2020 21:13:14
	System	22 Oct 2020 21:13:14

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:35:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-22T17:12:55', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '40b51bdf-2d30-42f1-9bcc-f283c8d987d4' User entered 'None (0)'	System	22 Oct 2020 21:13:14
	System	22 Oct 2020 21:13:14



US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:35:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-22T17:12:59', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '40b51bdf-2d30-42f1-9bcc-f283c8d987d4' User entered 'None (0)'	System	22 Oct 2020 21:13:14
	System	22 Oct 2020 21:13:14

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:35:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-22T17:13:03', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '40b51bdf-2d30-42f1-9bcc-f283c8d987d4' User entered 'None (0)'	System	22 Oct 2020 21:13:14
	System	22 Oct 2020 21:13:14

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:35:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-22T17:13:08', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '40b51bdf-2d30-42f1-9bcc-f283c8d987d4' User entered 'No (N)'	System	22 Oct 2020 21:13:14
	System	22 Oct 2020 21:13:14

**US3842060**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:35:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-22T17:13:11', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '40b51bdf-2d30-42f1-9bcc-f283c8d987d4' User entered '22 Oct 2020 17:13'	System	22 Oct 2020 21:13:14
	System	22 Oct 2020 21:13:14

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:35:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:35:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 3'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:35:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-23T12:04:03', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '973e7226-6311-47c2-9798-f7238ee72ae2' User entered 'None (0)'	System	23 Oct 2020 16:06:49
	System	23 Oct 2020 16:06:49



US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:35:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-23T12:04:08', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '973e7226-6311-47c2-9798-f7238ee72ae2' User entered 'None (0)'	System	23 Oct 2020 16:06:49
	System	23 Oct 2020 16:06:49

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:35:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-23T12:04:14', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '973e7226-6311-47c2-9798-f7238ee72ae2' User entered 'None (0)'	System	23 Oct 2020 16:06:49
	System	23 Oct 2020 16:06:49

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:35:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-23T12:04:20', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '973e7226-6311-47c2-9798-f7238ee72ae2' User entered 'None (0)'	System	23 Oct 2020 16:06:49
	System	23 Oct 2020 16:06:49

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:35:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-23T12:04:22', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '973e7226-6311-47c2-9798-f7238ee72ae2' User entered 'None (0)'	System	23 Oct 2020 16:06:49
	System	23 Oct 2020 16:06:49

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:35:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-23T12:04:25', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '973e7226-6311-47c2-9798-f7238ee72ae2' User entered 'None (0)'	System	23 Oct 2020 16:06:49
	System	23 Oct 2020 16:06:49

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:35:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-23T12:04:30', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '973e7226-6311-47c2-9798-f7238ee72ae2' User entered 'No (N)'	System	23 Oct 2020 16:06:49
	System	23 Oct 2020 16:06:49

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:35:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-23T12:04:33', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '973e7226-6311-47c2-9798-f7238ee72ae2' User entered '23 Oct 2020 12:04'	System	23 Oct 2020 16:06:49
	System	23 Oct 2020 16:06:49

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:35:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 19:49:42



US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:35:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 4'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:35:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-24T13:02:00', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'a282b5b0-1ae4-4295-9571-25509a4d4a09' User entered 'None (0)'	System	24 Oct 2020 17:02:24
	System	24 Oct 2020 17:02:24

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:35:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-24T13:02:06', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'a282b5b0-1ae4-4295-9571-25509a4d4a09' User entered 'None (0)'	System	24 Oct 2020 17:02:24
	System	24 Oct 2020 17:02:24

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:35:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-24T13:02:09', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'a282b5b0-1ae4-4295-9571-25509a4d4a09' User entered 'None (0)'	System	24 Oct 2020 17:02:24
	System	24 Oct 2020 17:02:24

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:35:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-24T13:02:10', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'a282b5b0-1ae4-4295-9571-25509a4d4a09' User entered 'None (0)'	System	24 Oct 2020 17:02:24
	System	24 Oct 2020 17:02:24

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:35:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-24T13:02:12', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'a282b5b0-1ae4-4295-9571-25509a4d4a09' User entered 'None (0)'	System	24 Oct 2020 17:02:24
	System	24 Oct 2020 17:02:24

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:35:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-24T13:02:14', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'a282b5b0-1ae4-4295-9571-25509a4d4a09' User entered 'None (0)'	System	24 Oct 2020 17:02:24
	System	24 Oct 2020 17:02:24



US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:35:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-24T13:02:20', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'a282b5b0-1ae4-4295-9571-25509a4d4a09' User entered 'No (N)'	System	24 Oct 2020 17:02:24
	System	24 Oct 2020 17:02:24

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:35:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-24T13:02:22', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'a282b5b0-1ae4-4295-9571-25509a4d4a09' User entered '24 Oct 2020 13:02'	System	24 Oct 2020 17:02:24
	System	24 Oct 2020 17:02:24

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:35:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '24 Oct 2020 12:00'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:35:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '25 Oct 2020 11:59'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 5'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:35:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-25T13:12:20', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '5d91caa0-06e7-40a0-9bca-014c5c61dda8' User entered 'None (0)'	System	25 Oct 2020 17:12:46
	System	25 Oct 2020 17:12:46

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:35:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-25T13:12:22', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '5d91caa0-06e7-40a0-9bca-014c5c61dda8' User entered 'None (0)'	System	25 Oct 2020 17:12:46
	System	25 Oct 2020 17:12:46

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:35:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-25T13:12:26', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '5d91caa0-06e7-40a0-9bca-014c5c61dda8' User entered 'None (0)'	System	25 Oct 2020 17:12:46
	System	25 Oct 2020 17:12:46



US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:35:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-25T13:12:29', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '5d91caa0-06e7-40a0-9bca-014c5c61dda8' User entered 'None (0)'	System	25 Oct 2020 17:12:46
	System	25 Oct 2020 17:12:46

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:35:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-25T13:12:32', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '5d91caa0-06e7-40a0-9bca-014c5c61dda8' User entered 'None (0)'	System	25 Oct 2020 17:12:46
	System	25 Oct 2020 17:12:46

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:35:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-25T13:12:37', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '5d91caa0-06e7-40a0-9bca-014c5c61dda8' User entered 'None (0)'	System	25 Oct 2020 17:12:46
	System	25 Oct 2020 17:12:46

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:35:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-25T13:12:40', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '5d91caa0-06e7-40a0-9bca-014c5c61dda8' User entered 'No (N)'	System	25 Oct 2020 17:12:46
	System	25 Oct 2020 17:12:46

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:35:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-25T13:12:43', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '5d91caa0-06e7-40a0-9bca-014c5c61dda8' User entered '25 Oct 2020 13:12'	System	25 Oct 2020 17:12:46
	System	25 Oct 2020 17:12:46

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:35:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '25 Oct 2020 12:00'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:35:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '26 Oct 2020 11:59'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 6'	System	21 Oct 2020 19:49:42



US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:35:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-26T16:39:16', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '1672818e-71a0-426b-ba84-e4ac992201d3' User entered 'None (0)'	System	26 Oct 2020 20:39:33
	System	26 Oct 2020 20:39:33

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:35:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-26T16:39:17', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '1672818e-71a0-426b-ba84-e4ac992201d3' User entered 'None (0)'	System	26 Oct 2020 20:39:33
	System	26 Oct 2020 20:39:33

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:35:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-26T16:39:19', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '1672818e-71a0-426b-ba84-e4ac992201d3' User entered 'None (0)'	System	26 Oct 2020 20:39:33
	System	26 Oct 2020 20:39:33

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:35:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-26T16:39:22', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '1672818e-71a0-426b-ba84-e4ac992201d3' User entered 'None (0)'	System	26 Oct 2020 20:39:33
	System	26 Oct 2020 20:39:33

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:35:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-26T16:39:24', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '1672818e-71a0-426b-ba84-e4ac992201d3' User entered 'None (0)'	System	26 Oct 2020 20:39:33
	System	26 Oct 2020 20:39:33

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:35:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-26T16:39:26', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '1672818e-71a0-426b-ba84-e4ac992201d3' User entered 'None (0)'	System	26 Oct 2020 20:39:33
	System	26 Oct 2020 20:39:33

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:35:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-26T16:39:28', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '1672818e-71a0-426b-ba84-e4ac992201d3' User entered 'No (N)'	System	26 Oct 2020 20:39:33
	System	26 Oct 2020 20:39:33

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:35:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-26T16:39:30', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '1672818e-71a0-426b-ba84-e4ac992201d3' User entered '26 Oct 2020 16:39'	System	26 Oct 2020 20:39:33
	System	26 Oct 2020 20:39:33



US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:35:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '26 Oct 2020 12:00'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:35:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '27 Oct 2020 11:59'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:35:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
Data entry locked.	System	21 Oct 2020 19:49:42
User entered 'Day 7'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:35:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-27T19:01:25', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'd78f557a-8956-48c6-80d7-05193bce9c27' User entered 'None (0)'	System	27 Oct 2020 23:02:15
	System	27 Oct 2020 23:02:15

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:35:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-27T19:01:27', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'd78f557a-8956-48c6-80d7-05193bce9c27' User entered 'None (0)'	System	27 Oct 2020 23:02:15
	System	27 Oct 2020 23:02:15

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:35:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-27T19:01:29', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'd78f557a-8956-48c6-80d7-05193bce9c27' User entered 'None (0)'	System	27 Oct 2020 23:02:15
	System	27 Oct 2020 23:02:15

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:35:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-27T19:01:31', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'd78f557a-8956-48c6-80d7-05193bce9c27' User entered 'None (0)'	System	27 Oct 2020 23:02:15
	System	27 Oct 2020 23:02:15

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:35:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-27T19:01:33', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'd78f557a-8956-48c6-80d7-05193bce9c27' User entered 'None (0)'	System	27 Oct 2020 23:02:15
	System	27 Oct 2020 23:02:15



US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:35:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-27T19:01:35', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'd78f557a-8956-48c6-80d7-05193bce9c27' User entered 'None (0)'	System	27 Oct 2020 23:02:15
	System	27 Oct 2020 23:02:15

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:35:38

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-27T19:02:08', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'd78f557a-8956-48c6-80d7-05193bce9c27'	System	27 Oct 2020 23:02:15
User entered 'No (N)'	System	27 Oct 2020 23:02:15

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:35:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-10-27T19:02:10', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'd78f557a-8956-48c6-80d7-05193bce9c27' User entered '27 Oct 2020 19:02'	System	27 Oct 2020 23:02:15
	System	27 Oct 2020 23:02:15

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:35:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '27 Oct 2020 12:00'	System	21 Oct 2020 19:49:42

US3842060

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:35:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:04:39
User entered '28 Oct 2020 11:59'	System	21 Oct 2020 19:49:42

**US3842060**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:35:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Yes (Y)'	(b) (4)	29 Oct 2020 21:36:22
	Christie Lyn Costanza	
	(b) (4)	

US3842060

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:35:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '29 Oct 2020'	(b) (4) Christie Lyn Costanza	29 Oct 2020 21:36:22
	(b) (4)	

US3842060

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:35:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	29 Oct 2020 21:36:22
	Christie Lyn Costanza	
	(b) (4)	



US3842060

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:35:38

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4)	29 Oct 2020 21:36:22
	Christie Lyn Costanza	
	(b) (4)	

US3842060

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:35:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Yes (Y)'	(b) (4)	29 Oct 2020 21:36:25
	Christie Lyn Costanza	
	(b) (4)	

**US3842060**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:35:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered 'I'	System	29 Oct 2020 21:36:25

**US3842060**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:35:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:25
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Yes (Y)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:21:13

US3842060

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:35:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:25
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '7 Nov 2020'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:21:13

US3842060

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:35:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:25
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:21:13

US3842060

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:35:38

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:25
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4)	18 Nov 2020 20:21:13
	Malithi Desilva (b) (4)	
	(b) (4)	

US3842060

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:35:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:25
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Yes (Y)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:21:04



**US3842060**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:35:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:25
User entered 'I'	System	18 Nov 2020 20:21:04

**US3842060**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:35:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:25
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Yes (Y)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:21:43

**US3842060**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:35:38**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:25
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '13 Nov 2020'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:21:43

US3842060

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:35:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:25
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:21:43

US3842060

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:35:38

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:25
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4)	18 Nov 2020 20:21:43
	Malithi Desilva (b) (4)	
	(b) (4)	

US3842060

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:35:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:25
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Yes (Y)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:21:47

**US3842060**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:35:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:25
User entered 'I'	System	18 Nov 2020 20:21:47

US3842060

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:35:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Yes (Y)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:22:00



US3842060

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:35:38

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '18 Nov 2020'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:22:00

US3842060

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:35:38

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Clinic (Clinic)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:22:00

**US3842060**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:35:38**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered 'VISIT2'	System	18 Nov 2020 20:22:00

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User accepted default value 'Pre-Dose (PREDOSE)'	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Yes (Y)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '18 Nov 2020'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '14:21'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered '18 Nov 2020 14:21'	System	18 Nov 2020 21:24:27



US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '98.1' F	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Oral (Oral)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '74'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered 'bpm'	System	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '16'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered 'breaths/min'	System	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '114'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27



US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered 'mmHg'	System	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '75'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered 'mmHg'	System	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User accepted default value 'Post-Dose (POSTDOSE)'	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'No (N)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered empty.	System	18 Nov 2020 21:24:27



US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered empty.	System	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered empty.	System	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27



US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered empty.	System	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered empty.	System	18 Nov 2020 21:24:27

US3842060

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:35:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'No (N)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:22:07

US3842060

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:35:38

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:22:07

US3842060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:35:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'No (N)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:22:38

US3842060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:35:38

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Other (OTHER)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:22:38

US3842060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:35:38

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'PROTOCOL DIRECTIVE VIA EPIP HAS REQUESTED THAT 2ND DOSE NOT BE ADMINISTERED. PARTICIPANT HAD A POSITIVE SALIVA TEST THAT WAS ADMINISTERED AT HIS WORKSITE.' reason for change: Data Entry Error	(b) (4)	18 Nov 2020 20:23:13
User entered empty.	Malithi Desilva (b) (4)	18 Nov 2020 20:22:38



US3842060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:35:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered empty.	System	18 Nov 2020 20:22:38

US3842060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:35:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:22:38

US3842060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:35:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:22:38

US3842060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:35:38

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered empty.	System	18 Nov 2020 20:22:38

US3842060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:35:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:22:38

US3842060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:35:38

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered empty.	System	18 Nov 2020 20:22:38

US3842060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:35:38

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered empty.	System	18 Nov 2020 20:22:38

US3842060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:35:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Yes (Y)'	(b) (4)	18 Nov 2020 20:54:38
	Mario Portilla (b) (4)	
	(b) (4)	



US3842060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:35:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '18 Nov 2020'	(b) (4)	18 Nov 2020 20:54:38
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:35:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	18 Nov 2020 20:57:12
User entered '14:40' reason for change: Data Entry Error	System	18 Nov 2020 20:57:12
	Mario Portilla (b) (4)	18 Nov 2020 20:57:12
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Nov 2020 20:54:38
User entered empty.	Mario Portilla (b) (4)	18 Nov 2020 20:54:38
	(b) (4)	

US3842060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:35:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered '18 Nov 2020 14:40'	System	18 Nov 2020 20:57:12
User entered empty.	System	18 Nov 2020 20:54:38

US3842060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:35:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '18 Nov 2020'	(b) (4)	18 Nov 2020 20:56:02
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:35:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mario Portilla (b) (4) (b) (4)	18 Nov 2020 20:56:02

US3842060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:35:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Yes (Y)'	(b) (4)	18 Nov 2020 20:56:02
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:35:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	(b) (4)	18 Nov 2020 20:56:46
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	18 Nov 2020 20:56:46
User entered '14:42' reason for change: Data Entry Error	Mario Portilla (b) (4)	18 Nov 2020 20:56:46
	(b) (4)	
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	18 Nov 2020 20:56:02
User entered empty.	Mario Portilla (b) (4)	18 Nov 2020 20:56:02
	(b) (4)	

**US3842060**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:35:38**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered '18 Nov 2020 14:42'	System	18 Nov 2020 20:56:46
User entered empty.	System	18 Nov 2020 20:56:02



US3842060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:35:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mario Portilla (b) (4) (b) (4)	18 Nov 2020 20:56:02

US3842060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:35:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Nov 2020 20:56:53
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Nov 2020 20:56:53
User entered 'No (N)' reason for change: Data Entry Error	Mario Portilla (b) (4)	18 Nov 2020 20:56:53
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 20:56:02
User entered empty.	Mario Portilla (b) (4)	18 Nov 2020 20:56:02
	(b) (4)	

US3842060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:35:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4)	18 Nov 2020 20:56:02
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:35:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered empty.	System	18 Nov 2020 20:56:02

US3842060

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:35:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Yes (Y)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:23:29

US3842060

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:35:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered '1'	System	18 Nov 2020 20:23:29

**US3842060**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:35:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Yes (Y)'	(b) (4)	13 Jan 2021 18:04:18
	Christie Lyn Costanza	
	(b) (4)	

US3842060

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:35:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '25 Nov 2020'	(b) (4) Christie Lyn Costanza	13 Jan 2021 18:04:18
	(b) (4)	



US3842060

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:35:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	13 Jan 2021 18:04:18
	Christie Lyn Costanza	
	(b) (4)	

**US3842060**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:35:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4)	13 Jan 2021 18:04:18
	Christie Lyn Costanza	
	(b) (4)	

US3842060

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:35:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:25
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Yes (Y)'	(b) (4)	16 Dec 2020 21:02:31
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:35:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:25
User entered '1'	System	16 Dec 2020 21:02:31

**US3842060**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:35:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Yes (Y)'	(b) (4)	13 Jan 2021 18:04:33
	Christie Lyn Costanza	
	(b) (4)	

US3842060

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:35:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '02 Dec 2020'	(b) (4)	13 Jan 2021 18:04:33
	Christie Lyn Costanza	
	(b) (4)	

US3842060

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:35:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	13 Jan 2021 18:04:33
	Christie Lyn Costanza	
	(b) (4)	

**US3842060**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:35:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4)	13 Jan 2021 18:04:33
	Christie Lyn Costanza	
	(b) (4)	



US3842060

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:35:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Yes (Y)'	(b) (4)	16 Dec 2020 21:02:50
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:35:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered 'I'	System	16 Dec 2020 21:02:50

**US3842060**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:35:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Yes (Y)'	(b) (4)	13 Jan 2021 18:04:45
	Christie Lyn Costanza	
	(b) (4)	

**US3842060**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:35:38**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '09 Dec 2020'	(b) (4)	13 Jan 2021 18:04:45
	Christie Lyn Costanza	
	(b) (4)	

US3842060

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:35:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Christie Lyn Costanza	13 Jan 2021 18:04:45

**US3842060**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:35:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4)	13 Jan 2021 18:04:45
	Christie Lyn Costanza	
	(b) (4)	

US3842060

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:35:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Yes (Y)'	(b) (4)	16 Dec 2020 21:03:10
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842060**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:35:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered 'I'	System	16 Dec 2020 21:03:10



US3842060

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:35:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Yes (Y)'	(b) (4)	16 Dec 2020 21:03:32
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842060**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:35:38**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '16 Dec 2020'	(b) (4)	16 Dec 2020 21:03:32
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:35:38

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Clinic (Clinic)'	(b) (4)	16 Dec 2020 21:03:32
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842060**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:35:38**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered 'VISIT3'	System	16 Dec 2020 21:03:32

US3842060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Yes (Y)'	(b) (4)	16 Dec 2020 21:06:26
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '16 Dec 2020'	(b) (4)	16 Dec 2020 21:06:26
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '11:43'	(b) (4)	16 Dec 2020 21:06:26
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered '16 Dec 2020 11:43'	System	16 Dec 2020 21:06:26



US3842060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '98.2' F	Mario Portilla (b) (4)	16 Dec 2020 21:06:26
	(b) (4)	

US3842060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Oral (Oral)'	(b) (4)	16 Dec 2020 21:06:26
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842060**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:35:38**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4)	16 Dec 2020 21:06:26
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '86'	(b) (4)	16 Dec 2020 21:06:26
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered 'bpm'	System	16 Dec 2020 21:06:26

US3842060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '16'	(b) (4)	16 Dec 2020 21:06:26
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered 'breaths/min'	System	16 Dec 2020 21:06:26

US3842060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '132'	(b) (4)	16 Dec 2020 21:06:26
	Mario Portilla (b) (4)	
	(b) (4)	



US3842060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered 'mmHg'	System	16 Dec 2020 21:06:26

US3842060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '83'	(b) (4)	16 Dec 2020 21:06:26
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered 'mmHg'	System	16 Dec 2020 21:06:26

US3842060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57

US3842060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57

US3842060

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:35:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'No (N)'	(b) (4)	16 Dec 2020 21:06:32
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:35:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4)	16 Dec 2020 21:06:32
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:35:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Yes (Y)'	(b) (4)	16 Dec 2020 21:07:18
	Mario Portilla (b) (4)	
	(b) (4)	



US3842060

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:35:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	16 Dec 2020 21:07:37
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).	System	16 Dec 2020 21:07:37
User entered '16 Dec 2020' reason for change: Data Entry Error	Mario Portilla (b) (4)	16 Dec 2020 21:07:37
	(b) (4)	
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	16 Dec 2020 21:07:18
User entered '12 Dec 2020'	Mario Portilla (b) (4)	16 Dec 2020 21:07:18
	(b) (4)	

US3842060

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:35:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '11:52'	(b) (4)	16 Dec 2020 21:07:18
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:35:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered '16 Dec 2020 11:52'	System	16 Dec 2020 21:07:37
User entered '12 Dec 2020 11:52'	System	16 Dec 2020 21:07:18

US3842060

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:35:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Yes (Y)'	(b) (4)	16 Dec 2020 21:07:42
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842060**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:35:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered '1'	System	16 Dec 2020 21:07:42

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-12-18T08:29:22', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'dbe89a83-126c-47cf-ade6-0363b4d7bfe4'	System	18 Dec 2020 13:29:57
User entered 'No (N)'	System	18 Dec 2020 13:29:57

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-12-18T08:29:33', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'dbe89a83-126c-47cf-ade6-0363b4d7bfe4' User entered 'No (N)'	System	18 Dec 2020 13:29:57
	System	18 Dec 2020 13:29:57



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-12-18T08:29:54', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'dbe89a83-126c-47cf-ade6-0363b4d7bfe4' User entered '18 Dec 2020 08:29:54'	System	18 Dec 2020 13:29:57
	System	18 Dec 2020 13:29:57

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-12-25T19:33:29', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '007f0792-c243-4864-a936-7e6ffebcf922'	System	26 Dec 2020 00:33:47
User entered 'No (N)'	System	26 Dec 2020 00:33:47

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-12-25T19:33:34', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '007f0792-c243-4864-a936-7e6ffebcf922'	System	26 Dec 2020 00:33:47
User entered 'No (N)'	System	26 Dec 2020 00:33:47

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2020-12-25T19:33:43', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '007f0792-c243-4864-a936-7e6ffebcf922'	System	26 Dec 2020 00:33:47
User entered '25 Dec 2020 19:33:43'	System	26 Dec 2020 00:33:47

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 13:21:55



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2021-01-01T00:13:41', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'a1f93205-04b4-43d1-b61b-1598fb800b0f' User entered 'No (N)'	System	01 Jan 2021 05:13:58
	System	01 Jan 2021 05:13:58

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2021-01-01T00:13:50', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'a1f93205-04b4-43d1-b61b-1598fb800b0f' User entered 'No (N)'	System	01 Jan 2021 05:13:58

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2021-01-01T00:13:57', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'a1f93205-04b4-43d1-b61b-1598fb800b0f' User entered '01 Jan 2021 00:13:57'	System	01 Jan 2021 05:13:58
	System	01 Jan 2021 05:13:58

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 13:21:55



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2021-01-08T05:10:47', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '3edd90ee-b5cc-42b5-9e87-1f1896ea255f' User entered 'No (N)'	System	08 Jan 2021 10:10:56
	System	08 Jan 2021 10:10:56

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2021-01-08T05:10:50', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '3edd90ee-b5cc-42b5-9e87-1f1896ea255f'	System	08 Jan 2021 10:10:56
User entered 'No (N)'	System	08 Jan 2021 10:10:56

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2021-01-08T05:10:53', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '3edd90ee-b5cc-42b5-9e87-1f1896ea255f' User entered '08 Jan 2021 05:10:53'	System	08 Jan 2021 10:10:56
	System	08 Jan 2021 10:10:56

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2021-01-15T08:46:59', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '3594562e-c2d5-4a01-af54-3db24c6ee26b' User entered 'No (N)'	System	15 Jan 2021 13:47:16
	System	15 Jan 2021 13:47:16

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2021-01-15T08:47:08', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '3594562e-c2d5-4a01-af54-3db24c6ee26b' User entered 'No (N)'	System	15 Jan 2021 13:47:16
	System	15 Jan 2021 13:47:16



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (591D8DF8-8B62-4123-AD9A-C3DAB5CE1C65)', Time: '2021-01-15T08:47:12', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '3594562e-c2d5-4a01-af54-3db24c6ee26b' User entered '15 Jan 2021 08:47:12'	System	15 Jan 2021 13:47:16

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 13:21:55



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F382EF5-4FFB-4192-B118-14A3E66FAE0D)', Time: '2021-02-13T12:04:32', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '88b72567-d406-4a2a-8f6e-8a4a4fde90b3' User entered 'No (N)'	System	13 Feb 2021 17:10:19
	System	13 Feb 2021 17:10:19

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F382EF5-4FFB-4192-B118-14A3E66FAE0D)', Time: '2021-02-13T12:04:39', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '88b72567-d406-4a2a-8f6e-8a4a4fde90b3' User entered 'No (N)'	System	13 Feb 2021 17:10:19
	System	13 Feb 2021 17:10:19

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F382EF5-4FFB-4192-B118-14A3E66FAE0D)', Time: '2021-02-13T12:04:43', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '88b72567-d406-4a2a-8f6e-8a4a4fde90b3' User entered '13 Feb 2021 12:04:43'	System	13 Feb 2021 17:10:19
	System	13 Feb 2021 17:10:19



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F382EF5-4FFB-4192-B118-14A3E66FAE0D)', Time: '2021-02-21T12:00:50', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '3a97f919-056c-4e5c-bca5-2987a2639c4f' User entered 'No (N)'	System	21 Feb 2021 17:05:17
	System	21 Feb 2021 17:05:17

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F382EF5-4FFB-4192-B118-14A3E66FAE0D)', Time: '2021-02-21T12:01:08', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '3a97f919-056c-4e5c-bca5-2987a2639c4f' User entered 'No (N)'	System	21 Feb 2021 17:05:17

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F382EF5-4FFB-4192-B118-14A3E66FAE0D)', Time: '2021-02-21T12:01:14', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '3a97f919-056c-4e5c-bca5-2987a2639c4f' User entered '21 Feb 2021 12:01:14'	System	21 Feb 2021 17:05:17
	System	21 Feb 2021 17:05:17

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 13:21:55



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F382EF5-4FFB-4192-B118-14A3E66FAE0D)', Time: '2021-02-26T12:40:12-05:00', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'e87646a4-80a1-49a0-912e-4c9a8407d70f' User entered 'No (N)'	System	26 Feb 2021 17:40:29
	System	26 Feb 2021 17:40:29

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F382EF5-4FFB-4192-B118-14A3E66FAE0D)', Time: '2021-02-26T12:40:17-05:00', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'e87646a4-80a1-49a0-912e-4c9a8407d70f' User entered 'No (N)'	System	26 Feb 2021 17:40:29
	System	26 Feb 2021 17:40:29

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F382EF5-4FFB-4192-B118-14A3E66FAE0D)', Time: '2021-02-26T12:40:26-05:00', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'e87646a4-80a1-49a0-912e-4c9a8407d70f' User entered '26 Feb 2021 17:40:26'	System	26 Feb 2021 17:40:29
	System	26 Feb 2021 17:40:29

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F382EF5-4FFB-4192-B118-14A3E66FAE0D)', Time: '2021-03-05T05:52:37-05:00', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '1bb4d0f0-aa4a-4b4c-9e9c-fbf3351ececa' User entered 'No (N)'	System	05 Mar 2021 10:52:51
	System	05 Mar 2021 10:52:51



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F382EF5-4FFB-4192-B118-14A3E66FAE0D)', Time: '2021-03-05T05:52:42-05:00', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '1bb4d0f0-aa4a-4b4c-9e9c-fbf3351ececa' User entered 'No (N)'	System	05 Mar 2021 10:52:51
	System	05 Mar 2021 10:52:51

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F382EF5-4FFB-4192-B118-14A3E66FAE0D)', Time: '2021-03-05T05:52:49-05:00', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '1bb4d0f0-aa4a-4b4c-9e9c-fbf3351ececa' User entered '05 Mar 2021 05:52:49'	System	05 Mar 2021 10:52:51
	System	05 Mar 2021 10:52:51

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F382EF5-4FFB-4192-B118-14A3E66FAE0D)', Time: '2021-03-12T05:14:51-05:00', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'bc1e8c38-7ed9-420f-9464-eeee80e6b0d9' User entered 'No (N)'	System	12 Mar 2021 10:15:01
	System	12 Mar 2021 10:15:01

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F382EF5-4FFB-4192-B118-14A3E66FAE0D)', Time: '2021-03-12T05:14:53-05:00', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'bc1e8c38-7ed9-420f-9464-eeee80e6b0d9' User entered 'No (N)'	System	12 Mar 2021 10:15:01
	System	12 Mar 2021 10:15:01

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F382EF5-4FFB-4192-B118-14A3E66FAE0D)', Time: '2021-03-12T05:14:55-05:00', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'bc1e8c38-7ed9-420f-9464-eeee80e6b0d9' User entered '12 Mar 2021 05:14:55'	System	12 Mar 2021 10:15:01
	System	12 Mar 2021 10:15:01



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F382EF5-4FFB-4192-B118-14A3E66FAE0D)', Time: '2021-03-19T05:20:30-04:00', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'cfaa1393-970d-4de3-b77b-ab5a59e55523'	System	19 Mar 2021 09:20:40
User entered 'No (N)'	System	19 Mar 2021 09:20:40

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F382EF5-4FFB-4192-B118-14A3E66FAE0D)', Time: '2021-03-19T05:20:32-04:00', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'cfaa1393-970d-4de3-b77b-ab5a59e55523'	System	19 Mar 2021 09:20:40
User entered 'No (N)'	System	19 Mar 2021 09:20:40

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F382EF5-4FFB-4192-B118-14A3E66FAE0D)', Time: '2021-03-19T05:20:35-04:00', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'cfaa1393-970d-4de3-b77b-ab5a59e55523' User entered '19 Mar 2021 05:20:35'	System	19 Mar 2021 09:20:40
	System	19 Mar 2021 09:20:40

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 13:21:55



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F382EF5-4FFB-4192-B118-14A3E66FAE0D)', Time: '2021-03-26T05:32:38-04:00', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'ae481216-16f7-4531-a06c-4e28db07a7fd'	System	26 Mar 2021 09:32:46
User entered 'No (N)'	System	26 Mar 2021 09:32:46

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F382EF5-4FFB-4192-B118-14A3E66FAE0D)', Time: '2021-03-26T05:32:40-04:00', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'ae481216-16f7-4531-a06c-4e28db07a7fd'	System	26 Mar 2021 09:32:46
User entered 'No (N)'	System	26 Mar 2021 09:32:46

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F382EF5-4FFB-4192-B118-14A3E66FAE0D)', Time: '2021-03-26T05:32:43-04:00', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'ae481216-16f7-4531-a06c-4e28db07a7fd' User entered '26 Mar 2021 05:32:43'	System	26 Mar 2021 09:32:46
	System	26 Mar 2021 09:32:46

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F382EF5-4FFB-4192-B118-14A3E66FAE0D)', Time: '2021-04-02T05:59:18-04:00', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'c48c2bcd-d607-4c5a-9b97-f8712a9a4525'	System	02 Apr 2021 09:59:28
User entered 'No (N)'	System	02 Apr 2021 09:59:28



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F382EF5-4FFB-4192-B118-14A3E66FAE0D)', Time: '2021-04-02T05:59:20-04:00', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'c48c2bcd-d607-4c5a-9b97-f8712a9a4525'	System	02 Apr 2021 09:59:28
User entered 'No (N)'	System	02 Apr 2021 09:59:28

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F382EF5-4FFB-4192-B118-14A3E66FAE0D)', Time: '2021-04-02T05:59:24-04:00', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'c48c2bcd-d607-4c5a-9b97-f8712a9a4525'	System	02 Apr 2021 09:59:28
User entered '02 Apr 2021 05:59:24'	System	02 Apr 2021 09:59:28

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F382EF5-4FFB-4192-B118-14A3E66FAE0D)', Time: '2021-04-09T05:56:54-04:00', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'de63b3c9-7324-4ef8-9e89-6c8dc1dc6ec7'	System	09 Apr 2021 09:57:02
User entered 'No (N)'	System	09 Apr 2021 09:57:02

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F382EF5-4FFB-4192-B118-14A3E66FAE0D)', Time: '2021-04-09T05:56:56-04:00', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'de63b3c9-7324-4ef8-9e89-6c8dc1dc6ec7' User entered 'No (N)'	System	09 Apr 2021 09:57:02

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F382EF5-4FFB-4192-B118-14A3E66FAE0D)', Time: '2021-04-09T05:56:58-04:00', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'de63b3c9-7324-4ef8-9e89-6c8dc1dc6ec7'	System	09 Apr 2021 09:57:02
User entered '09 Apr 2021 05:56:58'	System	09 Apr 2021 09:57:02



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F382EF5-4FFB-4192-B118-14A3E66FAE0D)', Time: '2021-04-16T05:57:46-04:00', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '5d4373f6-af5e-4603-8486-c792c8e0f4a2'	System	16 Apr 2021 09:57:54
User entered 'No (N)'	System	16 Apr 2021 09:57:54

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F382EF5-4FFB-4192-B118-14A3E66FAE0D)', Time: '2021-04-16T05:57:48-04:00', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '5d4373f6-af5e-4603-8486-c792c8e0f4a2'	System	16 Apr 2021 09:57:54
User entered 'No (N)'	System	16 Apr 2021 09:57:54

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F382EF5-4FFB-4192-B118-14A3E66FAE0D)', Time: '2021-04-16T05:57:52-04:00', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '5d4373f6-af5e-4603-8486-c792c8e0f4a2'	System	16 Apr 2021 09:57:54
User entered '16 Apr 2021 05:57:52'	System	16 Apr 2021 09:57:54

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 13:21:55



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F382EF5-4FFB-4192-B118-14A3E66FAE0D)', Time: '2021-04-23T05:21:08-04:00', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'ca81560a-d740-42df-ba7b-8a922c8afa85'	System	23 Apr 2021 09:21:15
User entered 'No (N)'	System	23 Apr 2021 09:21:15

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F382EF5-4FFB-4192-B118-14A3E66FAE0D)', Time: '2021-04-23T05:21:10-04:00', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'ca81560a-d740-42df-ba7b-8a922c8afa85'	System	23 Apr 2021 09:21:15
User entered 'No (N)'	System	23 Apr 2021 09:21:15

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F382EF5-4FFB-4192-B118-14A3E66FAE0D)', Time: '2021-04-23T05:21:13-04:00', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'ca81560a-d740-42df-ba7b-8a922c8afa85'	System	23 Apr 2021 09:21:15
User entered '23 Apr 2021 05:21:13'	System	23 Apr 2021 09:21:15

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F382EF5-4FFB-4192-B118-14A3E66FAE0D)', Time: '2021-04-30T05:33:54-04:00', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '5ae6fc82-e004-42e1-8de3-313d9e3919f3'	System	30 Apr 2021 09:34:02
User entered 'No (N)'	System	30 Apr 2021 09:34:02



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F382EF5-4FFB-4192-B118-14A3E66FAE0D)', Time: '2021-04-30T05:33:56-04:00', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '5ae6fc82-e004-42e1-8de3-313d9e3919f3' User entered 'No (N)'	System	30 Apr 2021 09:34:02

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F382EF5-4FFB-4192-B118-14A3E66FAE0D)', Time: '2021-04-30T05:33:58-04:00', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: '5ae6fc82-e004-42e1-8de3-313d9e3919f3' User entered '30 Apr 2021 05:33:58'	System	30 Apr 2021 09:34:02
	System	30 Apr 2021 09:34:02

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 13:21:55



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 13:21:55



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 13:21:55



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 13:21:55



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 13:21:55



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 13:21:55



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 13:21:55



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 13:21:55



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 13:21:55



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 13:21:55



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 13:21:55



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 13:21:55



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 13:21:55



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 13:21:55



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 13:21:55



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 13:21:55



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 13:21:55



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 13:21:55



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 13:21:55



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 13:21:55



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 13:21:55



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 13:21:55



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 13:21:55



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 13:21:55



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 13:21:55



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 13:21:55



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 13:21:55



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 13:21:55



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 13:21:55



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 13:21:55



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '11 Nov 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '15 Nov 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '18 Nov 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '22 Nov 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 13:21:55



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '25 Nov 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '29 Nov 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '02 Dec 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '06 Dec 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '09 Dec 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '13 Dec 2022 23:59'	System	20 Nov 2020 13:21:55



**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '16 Dec 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '20 Dec 2022 23:59'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '23 Dec 2022 00:01'	System	20 Nov 2020 13:21:55

**US3842060**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:35:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:21:55
Amendment Manager: User entered '27 Dec 2022 23:59'	System	20 Nov 2020 13:21:55

US3842060

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:35:38

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:58:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F382EF5-4FFB-4192-B118-14A3E66FAE0D)', Time: '2021-03-05T05:52:59-05:00', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'c5c0f7c0-7d27-4b9b-81b2-2a5c464fc401'	System	05 Mar 2021 10:53:40
User entered 'Yes (Y)'	System	05 Mar 2021 10:53:40

US3842060

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 12 Aug 2021 13:35:38**

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?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:58:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F382EF5-4FFB-4192-B118-14A3E66FAE0D)', Time: '2021-03-05T05:53:22-05:00', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'c5c0f7c0-7d27-4b9b-81b2-2a5c464fc401'	System	05 Mar 2021 10:53:40
User entered 'Yes (Y)'	System	05 Mar 2021 10:53:40



**US3842060**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 12 Aug 2021 13:35:38**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:58:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9F382EF5-4FFB-4192-B118-14A3E66FAE0D)', Time: '2021-03-05T05:53:29-05:00', User OID: 'PatientReportedOutcome (US3842060)', ODM File OID: 'c5c0f7c0-7d27-4b9b-81b2-2a5c464fc401' User entered '05 Mar 2021 05:53:29'	System	05 Mar 2021 10:53:40
	System	05 Mar 2021 10:53:40

**US3842060**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:35:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Yes (Y)'	(b) (4)	13 Jan 2021 18:05:05
	Christie Lyn Costanza	
	(b) (4)	

**US3842060**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:35:38**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '13 Jan 2021'	(b) (4)	13 Jan 2021 18:05:05
	Christie Lyn Costanza	
	(b) (4)	

**US3842060**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:35:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	13 Jan 2021 18:05:05
	Christie Lyn Costanza	
	(b) (4)	

**US3842060**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:35:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4)	13 Jan 2021 18:05:05
	Christie Lyn Costanza	
	(b) (4)	

US3842060

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:35:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Yes (Y)'	(b) (4) Christie Lyn Costanza	13 Jan 2021 18:05:09

**US3842060**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:35:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:25:57
User entered '1'	System	13 Jan 2021 18:05:09

**US3842060**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:35:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:11:21
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered 'Yes (Y)'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	26 Feb 2021 15:08:08



**US3842060**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:35:38**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:11:21
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered '19 Feb 2021'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	26 Feb 2021 15:08:08

US3842060

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:35:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:11:21
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	26 Feb 2021 15:08:08

US3842060

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:35:38

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:11:21
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered empty.	(b) (4) Zoraida Cruz (b) (4) (b) (4)	26 Feb 2021 15:08:08

US3842060

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:35:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:11:21
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	22 Jan 2021 20:26:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Jan 2021 20:26:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Malithi Desilva (b) (4)	22 Jan 2021 20:26:08
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Jan 2021 00:16:31
User entered empty; reason for change Data Entry Error	System	21 Jan 2021 00:16:31
User entered 'Yes (Y)'	Christie Lyn Costanza	21 Jan 2021 00:16:31
	(b) (4)	
	Christie Lyn Costanza	21 Jan 2021 00:09:43
	(b) (4)	

**US3842060**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:35:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:11:21
User entered '1'	System	22 Jan 2021 20:26:08
User entered empty.	System	21 Jan 2021 00:16:31
User entered '1'	System	21 Jan 2021 00:09:43

**US3842060**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:35:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:11:21
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:56:39
User entered 'Yes (Y)'	(b) (4)	19 Mar 2021 15:02:19
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842060**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:35:38**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:11:21
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:56:39
User entered '18 Mar 2021'	(b) (4)	19 Mar 2021 15:02:19
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842060**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:35:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:11:21
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:56:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	19 Mar 2021 15:02:19
	Mario Portilla (b) (4)	
	(b) (4)	



US3842060

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:35:38

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:11:21
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:56:39
User entered empty.	(b) (4)	19 Mar 2021 15:02:19
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:35:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:11:21
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:56:39
User entered 'Yes (Y)'	(b) (4)	19 Mar 2021 15:02:29
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842060**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:35:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:11:21
User entered '1'	System	19 Mar 2021 15:02:29

**US3842060**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:35:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:11:21
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:56:39
User entered 'Yes (Y)'	(b) (4)	22 Mar 2021 20:46:08
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:35:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:11:21
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:56:39
User entered '19 Mar 2021'	(b) (4)	22 Mar 2021 20:46:08
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842060**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:35:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:11:21
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:56:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	22 Mar 2021 20:46:08
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:35:38

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:11:21
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:56:39
User entered empty.	(b) (4)	22 Mar 2021 20:46:08
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:35:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:11:21
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:56:39
User entered 'Yes (Y)'	(b) (4)	22 Mar 2021 20:46:31
	Mario Portilla (b) (4)	
	(b) (4)	



**US3842060**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:35:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:11:21
User entered 'I'	System	22 Mar 2021 20:46:31

US3842060

Folder: Covid-19 Assessment 29 Oct 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:35:38

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:36:19
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '29 Oct 2020'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	23 Nov 2020 18:34:44

US3842060

Folder: Covid-19 Assessment 29 Oct 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:35:38

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:36:19
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '03:46'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	23 Nov 2020 18:34:44

US3842060

Folder: Covid-19 Assessment 29 Oct 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:35:38

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:36:19
User entered '29 Oct 2020 03:46'	System	23 Nov 2020 18:34:44

US3842060

Folder: Covid-19 Assessment 29 Oct 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:35:38

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:36:19
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Safety Call (Safety Call)'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	23 Nov 2020 18:34:44

US3842060

Folder: Covid-19 Assessment 29 Oct 2020

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:35:38

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:36:19
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'No (N)'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	23 Nov 2020 18:34:44

US3842060

Folder: Covid-19 Assessment 29 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 12 Aug 2021 13:35:38

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:36:19
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Yes (Y)'	(b) (4)	29 Jan 2021 03:02:11
	Christie Lyn Costanza	
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:35:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Yes (Y)'	Malithi Desilva (b) (4)	13 Jan 2021 22:48:06
	(b) (4)	



US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:35:38

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '13 Jan 2021'	Malithi Desilva (b) (4)	13 Jan 2021 22:48:06
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:35:38

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Clinic (Clinic)'	Malithi Desilva (b) (4)	13 Jan 2021 22:48:06
	(b) (4)	

**US3842060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:35:38**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered 'UNBLND_DECIDE'	System	13 Jan 2021 22:48:06

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:35:38

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '13 Jan 2021'	Malithi Desilva (b) (4)	13 Jan 2021 22:48:23
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:35:38

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:56:39
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:41:00

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:35:38

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User closed query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	(b) (4), (b) (6)	22 Jan 2021 07:46:17
Query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' answered with 'updated' (Site from System).	Christie Lyn Costanza	21 Jan 2021 00:10:09
	(b) (4)	
User opened query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System).	System	13 Jan 2021 22:48:23
User entered 'Yes (Y)'	Malithi Desilva (b) (4)	13 Jan 2021 22:48:23
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:35:38

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:56:39
	(b) (4)	
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 15:41:00

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:35:38

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '13 Jan 2021'	Malithi Desilva (b) (4)	13 Jan 2021 22:48:23
	(b) (4)	



US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:35:38

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Malithi Desilva (b) (4)	13 Jan 2021 22:48:23
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:35:38

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 16:19:09
User entered 'mRNA-1273 (mRNA-1273)'	Malithi Desilva (b) (4)	13 Jan 2021 22:48:23
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:35:38

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Not Administered (NA)' reason for change: Data Entry Error	Christie Lyn Costanza	21 Jan 2021 19:02:28
	(b) (4)	
User entered empty.	Malithi Desilva (b) (4)	13 Jan 2021 22:48:23
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:35:38

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Yes (Y)'	Malithi Desilva (b) (4)	13 Jan 2021 22:48:23
	(b) (4)	

**US3842060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 12 Aug 2021 13:35:38**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered empty.	System	13 Jan 2021 22:48:23

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:35:38

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered 'I'	System	21 Jan 2021 19:02:28
User entered empty.	System	13 Jan 2021 22:48:23

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:35:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered empty.	Mario Portilla (b) (4)	25 Jan 2021 22:43:53
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:35:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered empty.	Mario Portilla (b) (4)	25 Jan 2021 22:43:53
	(b) (4)	



US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:35:38

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered empty.	System	25 Jan 2021 22:43:53
DataPoint set to visible.	System	21 Jan 2021 19:02:28

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:35:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered empty.	Mario Portilla (b) (4)	25 Jan 2021 22:43:53
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:35:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered empty.	Mario Portilla (b) (4)	25 Jan 2021 22:43:53
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:35:38

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered empty.	System	25 Jan 2021 22:43:53
DataPoint set to visible.	System	21 Jan 2021 19:02:28

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User accepted default value 'Pre-Dose (PREDOSE)'	Mario Portilla (b) (4)	25 Jan 2021 22:43:53
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Yes (Y)'	Mario Portilla (b) (4)	25 Jan 2021 22:43:53
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '13 Jan 2021'	Mario Portilla (b) (4)	25 Jan 2021 22:43:53
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '14:43'	Mario Portilla (b) (4)	25 Jan 2021 22:43:53
	(b) (4)	



US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered '13 Jan 2021 14:43'	System	25 Jan 2021 22:43:53

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '99.1' F	Mario Portilla (b) (4)	25 Jan 2021 22:43:53
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Oral (Oral)'	Mario Portilla (b) (4)	25 Jan 2021 22:43:53
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered empty.	Mario Portilla (b) (4)	25 Jan 2021 22:43:53
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '70'	Mario Portilla (b) (4)	25 Jan 2021 22:43:53
	(b) (4)	

**US3842060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:35:38**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered 'bpm'	System	25 Jan 2021 22:43:53

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '12'	Mario Portilla (b) (4)	25 Jan 2021 22:43:53
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered 'breaths/min'	System	25 Jan 2021 22:43:53



US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '123'	Mario Portilla (b) (4)	25 Jan 2021 22:43:53
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered 'mmHg'	System	25 Jan 2021 22:43:53

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '75'	Mario Portilla (b) (4)	25 Jan 2021 22:43:53
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:35:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered 'mmHg'	System	25 Jan 2021 22:43:53

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:35:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered empty.	Mario Portilla (b) (4)	25 Jan 2021 22:43:53
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:35:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered empty.	Mario Portilla (b) (4)	25 Jan 2021 22:43:53
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:35:38

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered empty.	System	25 Jan 2021 22:43:53
DataPoint set to visible.	System	21 Jan 2021 19:02:28

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User accepted default value 'Post-Dose (POSTDOSE)'	Mario Portilla (b) (4)	25 Jan 2021 22:43:53
	(b) (4)	



US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 22:43:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Jan 2021 22:43:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Mario Portilla (b) (4)	25 Jan 2021 22:43:59
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 22:43:53
User entered empty.	Mario Portilla (b) (4)	25 Jan 2021 22:43:53
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '13 Jan 2021'	Mario Portilla (b) (4)	25 Jan 2021 22:43:53
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '17:18'	Mario Portilla (b) (4)	25 Jan 2021 22:43:53
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered '13 Jan 2021 17:18'	System	25 Jan 2021 22:43:53

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '98.7' F	Mario Portilla (b) (4)	25 Jan 2021 22:43:53
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Oral (Oral)'	Mario Portilla (b) (4)	25 Jan 2021 22:43:53
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered empty.	Mario Portilla (b) (4)	25 Jan 2021 22:43:53
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '71'	Mario Portilla (b) (4)	25 Jan 2021 22:43:53
	(b) (4)	



US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered 'bpm'	System	25 Jan 2021 22:43:53

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '12'	Mario Portilla (b) (4)	25 Jan 2021 22:43:53
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered 'breaths/min'	System	25 Jan 2021 22:43:53

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '122'	Mario Portilla (b) (4)	25 Jan 2021 22:43:53
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered 'mmHg'	System	25 Jan 2021 22:43:53

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '80'	Mario Portilla (b) (4)	25 Jan 2021 22:43:53
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:35:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered 'mmHg'	System	25 Jan 2021 22:43:53

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:35:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'No (N)'	Mario Portilla (b) (4)	25 Jan 2021 22:44:14
	(b) (4)	



US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:35:38

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered empty.	Mario Portilla (b) (4)	25 Jan 2021 22:44:14
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:35:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Yes (Y)'	Mario Portilla (b) (4)	25 Jan 2021 22:46:49
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:35:38

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered empty.	Mario Portilla (b) (4)	25 Jan 2021 22:46:49
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:35:38

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered empty.	Mario Portilla (b) (4)	25 Jan 2021 22:46:49
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:35:38

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered 'mRNA-1273'	System	25 Jan 2021 22:46:49
DataPoint set to visible.	System	21 Jan 2021 19:02:28

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:35:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '13 Jan 2021'	Mario Portilla (b) (4)	25 Jan 2021 22:46:49
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:35:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '16:43'	Mario Portilla (b) (4)	25 Jan 2021 22:46:49
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:35:38

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered '13 Jan 2021 16:43'	System	25 Jan 2021 22:46:49



US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:35:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Mario Portilla (b) (4)	25 Jan 2021 22:46:49
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:35:38

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered 'ONCE'	System	25 Jan 2021 22:46:49

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:35:38

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered 'INTRAMUSCULAR'	System	25 Jan 2021 22:46:49

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:35:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Yes (Y)'	Malithi Desilva (b) (4)	13 Jan 2021 22:50:50
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:35:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '13 Jan 2021'	Malithi Desilva (b) (4)	13 Jan 2021 22:50:50
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:35:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '15:16'	Malithi Desilva (b) (4)	13 Jan 2021 22:50:50
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:35:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered '13 Jan 2021 15:16'	System	13 Jan 2021 22:50:50

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:35:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Yes (Y)'	Malithi Desilva (b) (4)	13 Jan 2021 22:51:09
	(b) (4)	



US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:35:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '13 Jan 2021'	Malithi Desilva (b) (4)	13 Jan 2021 22:51:09
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:35:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '15:11'	Malithi Desilva (b) (4)	13 Jan 2021 22:51:09
	(b) (4)	

**US3842060**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 12 Aug 2021 13:35:38**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered '13 Jan 2021 15:11'	System	13 Jan 2021 22:51:09

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:35:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Yes (Y)'	Christie Lyn Costanza	21 Jan 2021 19:02:42
	(b) (4)	

US3842060

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:35:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 05:43:05
User entered '1'	System	21 Jan 2021 19:02:42

**US3842060**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:35:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:28
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Yes (Y)'	Christie Lyn Costanza	21 Jan 2021 19:03:15
	(b) (4)	

US3842060

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:35:38

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:28
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '20 Jan 2021'	Christie Lyn Costanza	21 Jan 2021 19:03:15
	(b) (4)	

**US3842060**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:35:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:28
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Christie Lyn Costanza	21 Jan 2021 19:03:15
	(b) (4)	



US3842060

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:35:38

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:28
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered empty.	Christie Lyn Costanza	21 Jan 2021 19:03:15
	(b) (4)	

US3842060

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:35:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:28
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Yes (Y)'	Christie Lyn Costanza	21 Jan 2021 19:03:19
	(b) (4)	

**US3842060**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:35:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:28
User entered 'I'	System	21 Jan 2021 19:03:19

US3842060

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:35:38

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:56:28
User entered 'I'	System	21 Jan 2021 19:03:19
DataPoint set to visible.	System	21 Jan 2021 19:03:19

**US3842060**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:35:38**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:26
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Yes (Y)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Feb 2021 16:43:26

**US3842060**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:35:38**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:26
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '10 Feb 2021'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Feb 2021 16:43:26

US3842060

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:35:38

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:26
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Clinic (Clinic)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Feb 2021 16:43:26

**US3842060**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:35:38**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:26
User entered 'OLD29'	System	10 Feb 2021 16:43:26



US3842060

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:26
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Yes (Y)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Feb 2021 16:44:42

US3842060

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:26
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '10 Feb 2021'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Feb 2021 16:44:42

**US3842060**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:35:38**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:26
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '10:54'	(b) (4)	10 Feb 2021 16:44:42
	Malithi Desilva (b) (4)	
	(b) (4)	

**US3842060**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:35:38**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:26
User entered '10 Feb 2021 10:54'	System	10 Feb 2021 16:44:42

US3842060

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:26
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '99.5' F	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Feb 2021 16:44:42

**US3842060**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:35:38**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:26
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Oral (Oral)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Feb 2021 16:44:42

**US3842060**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:35:38**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:26
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4)	10 Feb 2021 16:44:42
	Malithi Desilva (b) (4)	
	(b) (4)	

**US3842060**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:35:38**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:26
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '80'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Feb 2021 16:44:42



**US3842060**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:35:38**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:26
User entered 'bpm'	System	10 Feb 2021 16:44:42

US3842060

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:26
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '14'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Feb 2021 16:44:42

US3842060

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:26
User entered 'breaths/min'	System	10 Feb 2021 16:44:42

US3842060

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:26
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '120'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Feb 2021 16:44:42

US3842060

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:26
User entered 'mmHg'	System	10 Feb 2021 16:44:42

US3842060

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:26
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '83'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Feb 2021 16:44:42

US3842060

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:26
User entered 'mmHg'	System	10 Feb 2021 16:44:42

US3842060

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:26



US3842060

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:35:38

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:26

**US3842060**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:35:38**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:26
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'No (N)'	(b) (4)	10 Feb 2021 16:44:53
	Malithi Desilva (b) (4)	
	(b) (4)	

**US3842060**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:35:38**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:26
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4)	10 Feb 2021 16:44:53
	Malithi Desilva (b) (4)	
	(b) (4)	

**US3842060**

**Folder: OL-D29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:35:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:26
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Yes (Y)'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Feb 2021 16:45:07

US3842060

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:35:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:26
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '10 Feb 2021'	(b) (4) Malithi Desilva (b) (4) (b) (4)	10 Feb 2021 16:45:07

US3842060

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:35:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:26
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '11:06'	(b) (4)	10 Feb 2021 16:45:07
	Malithi Desilva (b) (4)	
	(b) (4)	

US3842060

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:35:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:01:26
User entered '10 Feb 2021 11:06'	System	10 Feb 2021 16:45:07

US3842060

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 13:35:38

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Mario Portilla (b) (4)	29 Oct 2020 22:13:25
User entered 'No (N)'	(b) (4) Mario Portilla (b) (4)	29 Oct 2020 22:13:01



US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:35:38

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User closed query 'Per CDM: Please review the condition and confirm. As per CCG (page 34), until the diagnosis is not confirmed COVID-19, the same should not be recorded at AE page.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:03:00
User closed query 'Per CDM: per sponsor review, Please consider changing AE name to Covid-19' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 13:59:40
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: Asymptomatic COVID-19, LLT: Asymptomatic COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 21:57:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 21:57:59
Query 'Per CDM: Please review the condition and confirm. As per CCG (page 34), until the diagnosis is not confirmed COVID-19, the same should not be recorded at AE page.' answered with 'error corrected.' (Site from DM).	Zoraida Cruz (b) (4) (b) (4)	23 Nov 2020 19:03:18
Query 'Per CDM: per sponsor review, Please consider changing AE name to Covid-19' answered with 'Error corrected AE name per query.' (Site from DM).	Zoraida Cruz (b) (4) (b) (4)	23 Nov 2020 18:38:19
Data point term sent to Coder	System	23 Nov 2020 18:37:55
Coding entries removed.	Zoraida Cruz (b) (4) (b) (4)	23 Nov 2020 18:37:35
User entered 'A-Symptomatic Covid-19' reason for change: Per Query Resolution	Zoraida Cruz (b) (4) (b) (4)	23 Nov 2020 18:37:35
User opened query 'Per CDM: Please review the condition and confirm. As per CCG (page 34), until the diagnosis is not confirmed COVID-19, the same should not be recorded at AE page.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 08:17:25
User opened query 'Per CDM: per sponsor review, Please consider changing AE name to Covid-19' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 13:38:50
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 13:38:43

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:35:38

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' answered with 'Participant assessed for COVID 19 symptoms 02NOV. Participant denies any symptoms to date. Resulted as not detected on 03NOV' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	17 Nov 2020 19:52:59
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 14:04:01
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: Asymptomatic COVID-19, LLT: Asymptomatic COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 23:28:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Oct 2020 23:28:54
Data point term sent to Coder	System	29 Oct 2020 22:27:43
User entered 'Asymptomatic COVID-19 reported by participant. Job requires weekly testing (saliva test) which was completed on Monday 10/26/2020 and results were reported to 2060 this date.'	Mario Portilla (b) (4) (b) (4)	29 Oct 2020 22:27:10

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:35:38**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
	(b) (4)	
User entered 'No (N)'	Mario Portilla (b) (4)	29 Oct 2020 22:27:10
	(b) (4)	

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:35:38**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
	(b) (4)	
User entered 'No (N)'	Mario Portilla (b) (4)	29 Oct 2020 22:27:10
	(b) (4)	

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:35:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if this a confirmed COVID Diagnosis. If yes, ensure this field is updated appropriately. Otherwise, provide clarification.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Shobha Swaminathan (b) (4)	02 Mar 2021 02:48:04 26 Feb 2021 19:04:25
Query 'Per DM CLR: Please review if this a confirmed COVID Diagnosis. If yes, ensure this field is updated appropriately. Otherwise, provide clarification.' answered with 'The Participant remained asymptomatic.' (Site from DM).	Zoraida Cruz (b) (4) (b) (4)	23 Feb 2021 21:31:07
User opened query 'Per DM CLR: Please review if this a confirmed COVID Diagnosis. If yes, ensure this field is updated appropriately. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 12:41:56
User entered 'No (N)'	Mario Portilla (b) (4) (b) (4)	29 Oct 2020 22:27:10

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:35:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
	(b) (4)	
User entered '26 Oct 2020' reason for change: Data Entry Error	Zoraida Cruz (b) (4)	23 Nov 2020 19:02:59
	(b) (4)	
User entered '28 Oct 2020'	Mario Portilla (b) (4)	29 Oct 2020 22:27:10
	(b) (4)	

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:35:38

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
	(b) (4)	
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	29 Oct 2020 22:29:12
User entered empty; reason for change Data Entry Error	Mario Portilla (b) (4)	29 Oct 2020 22:29:12
	(b) (4)	
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	29 Oct 2020 22:27:10
User entered '15:22'	Mario Portilla (b) (4)	29 Oct 2020 22:27:10
	(b) (4)	

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:35:38**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 22:29:12
User entered '28 Oct 2020 15:22'	System	29 Oct 2020 22:27:10



US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:35:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
	(b) (4)	
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	19 Nov 2020 19:21:20
User entered 'No (N)' reason for change: Data Entry Error	Mario Portilla (b) (4)	19 Nov 2020 19:21:20
	(b) (4)	
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	19 Nov 2020 19:20:57
User entered 'Yes (Y)'	Mario Portilla (b) (4)	29 Oct 2020 22:27:10
	(b) (4)	

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:35:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
	(b) (4)	
User entered '29 Oct 2020' reason for change: Data Entry Error	Malithi Desilva (b) (4)	10 Feb 2021 23:09:08
	(b) (4)	
User entered '26 Oct 2020' reason for change: Data Entry Error	Zoraida Cruz (b) (4)	23 Nov 2020 19:02:59
	(b) (4)	
User entered '29 Oct 2020' reason for change: Data Entry Error	Mario Portilla (b) (4)	19 Nov 2020 19:20:57
	(b) (4)	
User entered empty.	Mario Portilla (b) (4)	29 Oct 2020 22:27:10
	(b) (4)	

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:35:38**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
	(b) (4)	
User entered empty.	Mario Portilla (b) (4)	29 Oct 2020 22:27:10
	(b) (4)	

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:35:38**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 22:27:10

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:35:38**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Mario Portilla (b) (4)	29 Oct 2020 22:27:10
	(b) (4)	

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:35:38**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
	(b) (4)	
User entered 'No (N)'	Mario Portilla (b) (4)	29 Oct 2020 22:27:10
	(b) (4)	

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:35:38**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
	(b) (4)	
User entered '0'	Mario Portilla (b) (4)	29 Oct 2020 22:27:10
	(b) (4)	

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:35:38**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
	(b) (4)	
User entered '0'	Mario Portilla (b) (4)	29 Oct 2020 22:27:10
	(b) (4)	



US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:35:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
	(b) (4)	
User entered '0'	Mario Portilla (b) (4)	29 Oct 2020 22:27:10
	(b) (4)	

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:35:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
	(b) (4)	
User entered empty.	Mario Portilla (b) (4)	29 Oct 2020 22:27:10
	(b) (4)	

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:35:38

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
	(b) (4)	
User entered empty.	Mario Portilla (b) (4)	29 Oct 2020 22:27:10
	(b) (4)	

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:35:38**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
	(b) (4)	
User entered empty.	Mario Portilla (b) (4)	29 Oct 2020 22:27:10
	(b) (4)	

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:35:38**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
	(b) (4)	
User entered empty.	Mario Portilla (b) (4)	29 Oct 2020 22:27:10
	(b) (4)	

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:35:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
	(b) (4)	
User entered '0'	Mario Portilla (b) (4)	29 Oct 2020 22:27:10
	(b) (4)	

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:35:38**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
	(b) (4)	
User entered '0'	Mario Portilla (b) (4)	29 Oct 2020 22:27:10
	(b) (4)	

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:35:38**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
	(b) (4)	
User entered '0'	Mario Portilla (b) (4)	29 Oct 2020 22:27:10
	(b) (4)	



US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:35:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Mario Portilla (b) (4)	29 Oct 2020 22:27:10
	(b) (4)	

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:35:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Mario Portilla (b) (4)	29 Oct 2020 22:27:10
	(b) (4)	

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:35:38

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:01:30
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'The primary reason for discontinuation participant testing positive on a local test. per PPD even if asymptomatic should not receive the 2nd dose as it would be contraindicated per protocol.' (Site from System).	Zoraida Cruz (b) (4) (b) (4)	23 Nov 2020 19:09:14
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	23 Nov 2020 19:02:59
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Zoraida Cruz (b) (4) (b) (4)	23 Nov 2020 19:02:59
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Oct 2020 22:29:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Oct 2020 22:29:12
User entered 'None (NONE)' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	29 Oct 2020 22:29:12
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Oct 2020 22:27:10
User entered empty.	Mario Portilla (b) (4) (b) (4)	29 Oct 2020 22:27:10

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:35:38

None

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:56:39
	(b) (4)	
Signature has been broken.	Mario Portilla (b) (4)	09 Mar 2021 22:54:17
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
	(b) (4)	
User entered 'l'	Mario Portilla (b) (4)	29 Oct 2020 22:27:10
	(b) (4)	

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:35:38**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
	(b) (4)	
User entered '0'	Mario Portilla (b) (4)	29 Oct 2020 22:27:10
	(b) (4)	

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:35:38**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
	(b) (4)	
User entered '0'	Mario Portilla (b) (4)	29 Oct 2020 22:27:10
	(b) (4)	

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:35:38

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Mario Portilla (b) (4)	19 Nov 2020 19:20:57
Data Entry Error	(b) (4)	
User entered 'Unknown (UNKNOWN)'	Mario Portilla (b) (4)	29 Oct 2020 22:27:10
	(b) (4)	

US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:35:38

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
	(b) (4)	
User entered empty.	Mario Portilla (b) (4)	29 Oct 2020 22:27:10
	(b) (4)	



US3842060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:35:38

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered 'Participant positive on local saliva test, reported A-symptomatic. Confirmed with PPD, per protocol participant discontinued from receiving study product. Will continue study schedules and procedures.' reason for change: Data Entry Error	(b) (4) Zoraida Cruz (b) (4) (b) (4)	23 Nov 2020 19:02:59
User entered 'Participant will come to site for NP test. PMD will be notified per participant's consent in enrollment. Participant's employer is	Mario Portilla (b) (4) (b) (4) (b) (6)	29 Oct 2020 22:27:10
[REDACTED]		
[REDACTED]		
VISIT #2 is scheduled for Wednesday 18Nov2020. Pending outcome of confirmatory testing, site to follow protocol guidelines'		

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:35:38**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Oct 2020 22:27:10

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:35:38**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Oct 2020 22:27:10

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:35:38**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:01

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:35:38

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 14:02:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 14:02:59
Data point term sent to Coder	System	12 Feb 2021 16:12:03
Coding entries removed.	Malithi Desilva (b) (4)	12 Feb 2021 16:11:40
User entered 'ANXIETY R/T claustrophobia' reason for change: Data Entry Error	Malithi Desilva (b) (4)	12 Feb 2021 16:11:40
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 19:32:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 19:32:13
Data point term sent to Coder	System	19 Nov 2020 19:31:53
User entered 'Anxiety'	Mario Portilla (b) (4)	19 Nov 2020 19:31:03
	(b) (4)	

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:35:38

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered 'No (N)'	(b) (4)	19 Nov 2020 19:31:03
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:35:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User closed query 'Per sponsor review, please review and update field as Anxiety is not a solicited symptom from patient e-dairy. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Jan 2021 06:33:25
Query 'Per sponsor review, please review and update field as Anxiety is not a solicited symptom from patient e-dairy. ' answered with 'updated per query' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	30 Dec 2020 20:41:10
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	30 Dec 2020 20:41:02
User opened query 'Per sponsor review, please review and update field as Anxiety is not a solicited symptom from patient e-dairy. ' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 20:55:05
User entered 'Yes (Y)'	Mario Portilla (b) (4) (b) (4)	19 Nov 2020 19:31:03

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:35:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered 'No (N)'	(b) (4)	19 Nov 2020 19:31:03
	Mario Portilla (b) (4)	
	(b) (4)	



**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:35:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered '17 Nov 2020'	(b) (4)	19 Nov 2020 19:31:03
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:35:38**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered empty.	(b) (4)	19 Nov 2020 19:31:03
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:35:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:01
User entered empty.	System	19 Nov 2020 19:31:03

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:35:38**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered 'No (N)'	(b) (4)	19 Nov 2020 19:31:03
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:35:38

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered '17 Nov 2020'	(b) (4)	19 Nov 2020 19:31:03
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:35:38**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered empty.	(b) (4)	19 Nov 2020 19:31:03
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:35:38**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:01
User entered empty.	System	19 Nov 2020 19:31:03

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:35:38

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	19 Nov 2020 19:31:03
	Mario Portilla (b) (4)	
	(b) (4)	



US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:35:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered 'No (N)'	(b) (4)	19 Nov 2020 19:31:03
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:35:38**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered '0'	(b) (4)	19 Nov 2020 19:31:03
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:35:38**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered '0'	(b) (4)	19 Nov 2020 19:31:03
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:35:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered '0'	(b) (4)	19 Nov 2020 19:31:03
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:35:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered empty.	(b) (4)	19 Nov 2020 19:31:03
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:35:38

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered empty.	(b) (4)	19 Nov 2020 19:31:03
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:35:38**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered empty.	(b) (4)	19 Nov 2020 19:31:03
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:35:38**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered empty.	(b) (4)	19 Nov 2020 19:31:03
	Mario Portilla (b) (4)	
	(b) (4)	



US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:35:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered '0'	(b) (4)	19 Nov 2020 19:31:03
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:35:38

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered '0'	(b) (4)	19 Nov 2020 19:31:03
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:35:38

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered '0'	(b) (4)	19 Nov 2020 19:31:03
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:35:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered 'Not Related (NOT RELATED)'	(b) (4)	19 Nov 2020 19:31:03
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:35:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered 'Not Related (NOT RELATED)'	(b) (4)	19 Nov 2020 19:31:03
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:35:38

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Nov 2020 19:13:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Nov 2020 19:13:03
User entered 'None (NONE)' reason for change: Data Entry Error	Zoraida Cruz (b) (4)	23 Nov 2020 19:13:03
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Nov 2020 19:31:03
User entered empty.	System	19 Nov 2020 19:31:03
	Mario Portilla (b) (4)	19 Nov 2020 19:31:03
	(b) (4)	

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:35:38**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered '0'	(b) (4)	19 Nov 2020 19:31:03
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:35:38**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered 'I'	(b) (4)	19 Nov 2020 19:31:03
	Mario Portilla (b) (4)	
	(b) (4)	



US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:35:38

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered '0'	(b) (4)	19 Nov 2020 19:31:03
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:35:38**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Mario Portilla (b) (4) (b) (4)	19 Nov 2020 19:31:03

US3842060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:35:38

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered empty.	(b) (4)	19 Nov 2020 19:31:03
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:35:38**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:01
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered 'Anxiety related to MRI induced claustrophobia'	(b) (4) Mario Portilla (b) (4) (b) (4)	19 Nov 2020 19:31:03

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:35:38**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:01
User entered '0'	System	19 Nov 2020 19:31:03

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:35:38**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:01
User entered '0'	System	19 Nov 2020 19:31:03

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:35:38**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:01

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:35:38**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:03



US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:35:38

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:03
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Fear symptoms and phobic disorders (incl social phobia), PT: Claustrophobia, LLT: Claustrophobia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	19 Nov 2020 19:36:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 19:36:01
Data point term sent to Coder	System	19 Nov 2020 19:34:59
User entered 'Claustrophobia'	Mario Portilla (b) (4) (b) (4)	19 Nov 2020 19:34:45

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:35:38**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:03
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered 'No (N)'	(b) (4)	19 Nov 2020 19:34:45
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:35:38

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:03
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User closed query 'Per sponsor review, please review and update field as Claustrophobia is not a solicited symptom from patient e-dairy. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Jan 2021 06:33:35
Query 'Per sponsor review, please review and update field as Claustrophobia is not a solicited symptom from patient e-dairy. ' answered with 'updated per query' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	30 Dec 2020 20:41:38
User entered 'No (N)' reason for change: Data Entry Error	Malithi Desilva (b) (4) (b) (4)	30 Dec 2020 20:41:25
User opened query 'Per sponsor review, please review and update field as Claustrophobia is not a solicited symptom from patient e-dairy. ' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 20:55:20
User entered 'Yes (Y)'	Mario Portilla (b) (4) (b) (4)	19 Nov 2020 19:34:45

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:35:38

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:03
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered 'No (N)'	(b) (4)	19 Nov 2020 19:34:45
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:35:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:03
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered '17 Nov 2020'	(b) (4)	19 Nov 2020 19:34:45
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:35:38**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:03
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered empty.	(b) (4)	19 Nov 2020 19:34:45
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:35:38

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:03
User entered empty.	System	19 Nov 2020 19:34:45

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:35:38**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:03
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered 'No (N)'	(b) (4)	19 Nov 2020 19:34:45
	Mario Portilla (b) (4)	
	(b) (4)	



**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:35:38**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:03
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered '17 Nov 2020'	(b) (4)	19 Nov 2020 19:34:45
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:35:38**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:03
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered empty.	(b) (4)	19 Nov 2020 19:34:45
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:35:38

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:03
User entered empty.	System	19 Nov 2020 19:34:45

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:35:38

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:03
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	19 Nov 2020 19:34:45
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:35:38

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:03
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered 'No (N)'	(b) (4)	19 Nov 2020 19:34:45
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:35:38**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:03
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered '0'	(b) (4)	19 Nov 2020 19:34:45
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:35:38**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:03
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered '0'	(b) (4)	19 Nov 2020 19:34:45
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:35:38

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:03
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered '0'	(b) (4)	19 Nov 2020 19:34:45
	Mario Portilla (b) (4)	
	(b) (4)	



US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:35:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:03
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered empty.	(b) (4)	19 Nov 2020 19:34:45
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:35:38

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:03
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered empty.	(b) (4)	19 Nov 2020 19:34:45
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:35:38**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:03
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered empty.	(b) (4)	19 Nov 2020 19:34:45
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:35:38**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:03
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered empty.	(b) (4)	19 Nov 2020 19:34:45
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:35:38

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:03
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered '0'	(b) (4)	19 Nov 2020 19:34:45
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:35:38**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:03
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered '0'	(b) (4)	19 Nov 2020 19:34:45
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:35:38

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:03
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered '0'	(b) (4)	19 Nov 2020 19:34:45
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:35:38

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:03
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered 'Not Related (NOT RELATED)'	(b) (4)	19 Nov 2020 19:34:45
	Mario Portilla (b) (4)	
	(b) (4)	



US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:35:38

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:03
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered 'Not Related (NOT RELATED)'	(b) (4)	19 Nov 2020 19:34:45
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:35:38**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:03
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered 'None (NONE)'	(b) (4)	19 Nov 2020 19:34:45
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:35:38**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:03
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered '0'	(b) (4)	19 Nov 2020 19:34:45
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:35:38

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:03
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered 'I'	(b) (4)	19 Nov 2020 19:34:45
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:35:38**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:03
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered '0'	(b) (4)	19 Nov 2020 19:34:45
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:35:38**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:03
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Mario Portilla (b) (4) (b) (4)	19 Nov 2020 19:34:45

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:35:38

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:03
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered empty.	(b) (4)	19 Nov 2020 19:34:45
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:35:38

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:03
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User entered 'Claustrophobia induced by MRI'	(b) (4)	19 Nov 2020 19:34:45
	Mario Portilla (b) (4)	
	(b) (4)	



**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:35:38**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:03
User entered '0'	System	19 Nov 2020 19:34:45

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:35:38**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:03
User entered '0'	System	19 Nov 2020 19:34:45

**US3842060**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 12 Aug 2021 13:35:38**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:10:03

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 12 Aug 2021 13:35:38**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:18
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Yes (Y)'	(b) (4) Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:32:52

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:35:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Oct 2020 05:02:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 05:02:28
Data point term sent to Coder	System	21 Oct 2020 19:36:27
User entered 'Simvastatin'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:36:16

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:35:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, please confirm whether there is an existing actual condition requiring this medication. If confirmed yes, please ensure that there is a corresponding MH/AE condition recorded that matches this medication and review if the prophylaxis field should be changed to NO, as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 11:58:42
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
Query 'Per DM CLR: Prophylaxis is marked as YES. However, please confirm whether there is an existing actual condition requiring this medication. If confirmed yes, please ensure that there is a corresponding MH/AE condition recorded that matches this medication and review if the prophylaxis field should be changed to NO, as appropriate. Otherwise, provide clarification. ' answered with 'participant has no MH/AE condition corresponding to indication. participant taking medication as a preventive measure hence why prophylaxis marked yes. ' (Site from DM).	(b) (4) Malithi Desilva (b) (4)	10 Feb 2021 22:53:39
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, please confirm whether there is an existing actual condition requiring this medication. If confirmed yes, please ensure that there is a corresponding MH/AE condition recorded that matches this medication and review if the prophylaxis field should be changed to NO, as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 02:56:59
User entered 'Yes (Y)'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:36:16

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:35:38**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Reduce Risk of MI or Brain Attack'	Zoraida Cruz (b) (4)	21 Oct 2020 19:36:16
	(b) (4)	

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:35:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '20'	Zoraida Cruz (b) (4)	21 Oct 2020 19:36:16
	(b) (4)	



US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:35:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'mg (mg)'	Zoraida Cruz (b) (4)	21 Oct 2020 19:36:16
	(b) (4)	

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:35:38**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	21 Oct 2020 19:36:16
	(b) (4)	

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:35:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'as needed (PRN)' reason for change:	Malithi Desilva (b) (4)	02 Dec 2020 18:03:27
Data Entry Error	(b) (4)	
User entered 'other (OTHER)'	Zoraida Cruz (b) (4)	21 Oct 2020 19:36:16
	(b) (4)	

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:35:38

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User closed query 'Per CDM: Response noted, however kindly up "OCCASIONAL" to note actual Frequency in accordance to CCGs. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 09:52:21
Query 'Per CDM: Response noted, however kindly up "OCCASIONAL" to note actual Frequency in accordance to CCGs. Thank you. ' answered with 'confirmed with site RN, corrected frequency ' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	02 Dec 2020 18:03:55
User entered empty; reason for change Data Entry Error	Malithi Desilva (b) (4) (b) (4)	02 Dec 2020 18:03:27
User opened query 'Per CDM: Response noted, however kindly up "OCCASIONAL" to note actual Frequency in accordance to CCGs. Thank you. ' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 12:53:38
User entered 'occasional'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:36:16

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:35:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Oral (ORAL)'	Zoraida Cruz (b) (4)	21 Oct 2020 19:36:16
	(b) (4)	

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:35:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	21 Oct 2020 19:36:16
	(b) (4)	

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:35:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'un UNK 2019'	Zoraida Cruz (b) (4)	21 Oct 2020 19:36:16
	(b) (4)	

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:35:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '0'	Zoraida Cruz (b) (4)	21 Oct 2020 19:36:16
	(b) (4)	



US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:35:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Yes (Y)'	Zoraida Cruz (b) (4)	21 Oct 2020 19:36:16
	(b) (4)	

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:35:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	21 Oct 2020 19:36:16
	(b) (4)	

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:35:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'No (N)'	Zoraida Cruz (b) (4)	21 Oct 2020 19:36:16
	(b) (4)	

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:35:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 19:36:16

**US3842060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:35:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 19:36:16

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:35:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 19:36:16

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:35:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Oct 2020 19:49:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 19:49:34
Data point term sent to Coder	System	21 Oct 2020 19:48:49
User entered 'Vitamin B12'	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:48:18

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:35:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Yes (Y)'	Zoraida Cruz (b) (4)	21 Oct 2020 19:48:18
	(b) (4)	



US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:35:38**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Nutritional Supplement'	Zoraida Cruz (b) (4)	21 Oct 2020 19:48:18
	(b) (4)	

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:35:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '1'	Zoraida Cruz (b) (4)	21 Oct 2020 19:48:18
	(b) (4)	

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:35:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'tablet (TABLET)'	Zoraida Cruz (b) (4)	21 Oct 2020 19:48:18
	(b) (4)	

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:35:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	21 Oct 2020 19:48:18
	(b) (4)	

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:35:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'as needed (PRN)' reason for change: Per Query Resolution	Malithi Desilva (b) (4)	21 Jan 2021 22:55:37
	(b) (4)	
User entered 'other (OTHER)' reason for change: Data Entry Error	Mario Portilla (b) (4)	29 Dec 2020 21:17:32
	(b) (4)	
User entered 'once daily (QD)'	Zoraida Cruz (b) (4)	21 Oct 2020 19:48:18
	(b) (4)	

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:35:38

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User closed query 'Per CDM RQ: Response noted, however kindly up "OCCASIONALLY" to note actual Frequency in accordance to CCGs. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:21:39
Query 'Per CDM RQ: Response noted, however kindly up "OCCASIONALLY" to note actual Frequency in accordance to CCGs. Thank you.' answered with 'frequency updated in accordance to CCGs from occasionally to PRN, as needed, confirmed with study nurse and participant' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	25 Jan 2021 17:03:12
User opened query 'Per CDM RQ: Response noted, however kindly up "OCCASIONALLY" to note actual Frequency in accordance to CCGs. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 13:11:31
User closed query 'Per CDM: Response noted, however kindly up "OCCASIONALLY" to note actual Frequency in accordance to CCGs. Thank you.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 13:11:18
Query 'Per CDM: Response noted, however kindly up "OCCASIONALLY" to note actual Frequency in accordance to CCGs. Thank you.' answered with 'updated per CCG' (Site from DM).	Malithi Desilva (b) (4) (b) (4)	21 Jan 2021 22:55:51
User entered empty; reason for change Per Query Resolution	Malithi Desilva (b) (4) (b) (4)	21 Jan 2021 22:55:37
User opened query 'Per CDM: Response noted, however kindly up "OCCASIONALLY" to note actual Frequency in accordance to CCGs. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 10:26:56
User entered 'occasionally' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	29 Dec 2020 21:17:32
User entered empty.	Zoraida Cruz (b) (4) (b) (4)	21 Oct 2020 19:48:18

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:35:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Oral (ORAL)'	Zoraida Cruz (b) (4)	21 Oct 2020 19:48:18
	(b) (4)	

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:35:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	21 Oct 2020 19:48:18
	(b) (4)	



US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:35:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'un UNK 2016'	Zoraida Cruz (b) (4)	21 Oct 2020 19:48:18
	(b) (4)	

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:35:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '0'	Zoraida Cruz (b) (4)	21 Oct 2020 19:48:18
	(b) (4)	

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:35:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Yes (Y)'	Zoraida Cruz (b) (4)	21 Oct 2020 19:48:18
	(b) (4)	

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:35:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered empty.	Zoraida Cruz (b) (4)	21 Oct 2020 19:48:18
	(b) (4)	

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:35:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'No (N)'	Zoraida Cruz (b) (4)	21 Oct 2020 19:48:18
	(b) (4)	

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:35:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Dec 2020 21:17:32
User entered '1'	System	21 Oct 2020 19:48:18

**US3842060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:35:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Dec 2020 21:17:32
User entered '1'	System	21 Oct 2020 19:48:18

**US3842060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:35:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Dec 2020 21:17:32
User entered '804 (804)'	System	21 Oct 2020 19:48:18



US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:35:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:19
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: DIAZEPAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Nov 2020 22:24:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 22:24:48
Data point term sent to Coder	System	19 Nov 2020 19:15:16
Data point term sent to Coder	System	19 Nov 2020 19:11:07
User entered 'diazepam'	Mario Portilla (b) (4) (b) (4)	19 Nov 2020 19:10:56

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:35:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:19
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'No (N)'	(b) (4)	19 Nov 2020 19:10:56
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:35:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:19
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'ANXIETY RELATED TO MRI induced claustrophobia' reason for change: Data Entry Error	(b) (4) Mario Portilla (b) (4)	19 Nov 2020 19:14:51
User entered 'anxiety related to claustrophobia in MRI'	(b) (4) Mario Portilla (b) (4)	19 Nov 2020 19:10:56

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:35:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:19
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide comment for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 11:58:58
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide comment for alternate dosage.' answered with 'confirmed with study nurse and updated' (Site from DM).	(b) (4) Malithi Desilva (b) (4)	10 Feb 2021 22:56:41
User entered '2.5' reason for change: Data Entry Error	(b) (4)	10 Feb 2021 22:56:28
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide comment for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 06:03:12
User entered '25'	Mario Portilla (b) (4) (b) (4)	19 Nov 2020 19:10:56

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:35:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:19
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'mg (mg)'	Mario Portilla (b) (4)	19 Nov 2020 19:10:56
	(b) (4)	

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:35:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:19
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4)	19 Nov 2020 19:10:56
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:35:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:19
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'twice daily (BID)'	(b) (4)	19 Nov 2020 19:10:56
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:35:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:19
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4)	19 Nov 2020 19:10:56
	Mario Portilla (b) (4)	
	(b) (4)	



US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:35:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:19
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Oral (ORAL)'	(b) (4)	19 Nov 2020 19:10:56
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:35:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:19
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4)	19 Nov 2020 19:10:56
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:35:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:19
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '17 Nov 2020'	(b) (4)	19 Nov 2020 19:10:56
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:35:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:19
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '0'	(b) (4)	19 Nov 2020 19:10:56
	Mario Portilla (b) (4)	
	(b) (4)	

**US3842060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:35:38**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:19
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'No (N)'	(b) (4)	19 Nov 2020 19:10:56
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:35:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:19
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered '17 Nov 2020'	(b) (4)	19 Nov 2020 19:10:56
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:35:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:19
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Shobha Swaminathan (b) (4)	17 Feb 2021 11:59:01 16 Feb 2021 18:57:14
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update as appropriate. Otherwise, provide clarification.' answered with 'reviewed and updated per query' (Site from DM). User entered 'No (N)' reason for change: Per Query Resolution	Malithi Desilva (b) (4) (b) (4) Malithi Desilva (b) (4) (b) (4)	10 Feb 2021 22:56:56 10 Feb 2021 22:56:28
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6) Mario Portilla (b) (4) (b) (4)	27 Jan 2021 06:03:25 19 Nov 2020 19:10:56

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:35:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:19
User entered '2'	System	19 Nov 2020 19:10:56



US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:35:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:19
User entered '1'	System	19 Nov 2020 19:10:56

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:35:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:20:19
User entered '804 (804)'	System	19 Nov 2020 19:10:56

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:35:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: ZINC, PRODUCT: ZINC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Jan 2021 19:35:57
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Jan 2021 19:35:57
	(b) (4)	
Data point term sent to Coder	System	14 Jan 2021 19:35:19
User entered 'Zinc'	Christie Lyn Costanza	14 Jan 2021 19:35:12
	(b) (4)	

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:35:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User closed query 'Per DM CLR: Please review response as supplements are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 09:01:58
Query 'Per DM CLR: Please review response as supplements are considered as prophylaxis. Update as appropriate. ' answered with 'error corrected and updated to indicate Zinc as a prophylaxis' (Site from DM). Signature has been broken.	Zoraida Cruz (b) (4) (b) (4)	23 Feb 2021 21:33:36
User entered 'Yes (Y)' reason for change: Data Entry Error	Zoraida Cruz (b) (4) (b) (4)	23 Feb 2021 21:32:44
User opened query 'Per DM CLR: Please review response as supplements are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 07:21:49
User signature succeeded.	Shobha Swaminathan (b) (4)	16 Feb 2021 18:57:14
User entered 'No (N)'	Christie Lyn Costanza (b) (4)	14 Jan 2021 19:35:12

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:35:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Nutritional Supplement'	Christie Lyn Costanza	14 Jan 2021 19:35:12
	(b) (4)	

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:35:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '50' reason for change: Data Entry Error	Mario Portilla (b) (4)	25 Jan 2021 22:49:13
	(b) (4)	
User entered '1'	Christie Lyn Costanza	14 Jan 2021 19:35:12
	(b) (4)	

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:35:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	Mario Portilla (b) (4)	25 Jan 2021 22:49:13
	(b) (4)	
User entered 'tablet (TABLET)'	Christie Lyn Costanza	14 Jan 2021 19:35:12
	(b) (4)	

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:35:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered empty.	Christie Lyn Costanza	14 Jan 2021 19:35:12
	(b) (4)	



US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:35:38**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'as needed (PRN)'	Christie Lyn Costanza	14 Jan 2021 19:35:12
	(b) (4)	

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:35:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered empty.	Christie Lyn Costanza	14 Jan 2021 19:35:12
	(b) (4)	

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:35:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Oral (ORAL)'	Christie Lyn Costanza	14 Jan 2021 19:35:12
	(b) (4)	

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:35:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered empty.	Christie Lyn Costanza	14 Jan 2021 19:35:12
	(b) (4)	

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:35:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'un Dec 2020'	Christie Lyn Costanza	14 Jan 2021 19:35:12
	(b) (4)	

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:35:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '0'	Christie Lyn Costanza	14 Jan 2021 19:35:12
	(b) (4)	

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:35:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Yes (Y)'	Christie Lyn Costanza	14 Jan 2021 19:35:12
	(b) (4)	

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:35:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered empty.	Christie Lyn Costanza	14 Jan 2021 19:35:12
	(b) (4)	



US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:35:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'No (N)'	Christie Lyn Costanza	14 Jan 2021 19:35:12
	(b) (4)	

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:35:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Jan 2021 19:35:12

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:35:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Jan 2021 19:35:12

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:35:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Jan 2021 19:35:12

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:35:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Jan 2021 19:36:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Jan 2021 19:36:57
Data point term sent to Coder	System	14 Jan 2021 19:36:20
User entered 'Vitamin D'	Christie Lyn Costanza (b) (4)	14 Jan 2021 19:35:53

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:35:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	26 Feb 2021 19:04:25
User closed query 'Per DM CLR: Please review response as supplements/vitamins are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 09:33:01
Query 'Per DM CLR: Please review response as supplements/vitamins are considered as prophylaxis. Update as appropriate. ' answered with 'error corrected and updated to indicate Zinc as a prophylaxis' (Site from DM).	Zoraida Cruz (b) (4) (b) (4)	23 Feb 2021 21:34:10
Signature has been broken.	Zoraida Cruz (b) (4) (b) (4)	23 Feb 2021 21:34:03
User entered 'Yes (Y)' reason for change: Data Entry Error	Zoraida Cruz (b) (4) (b) (4)	23 Feb 2021 21:34:03
User opened query 'Per DM CLR: Please review response as supplements/vitamins are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 07:21:34
User signature succeeded.	Shobha Swaminathan (b) (4)	16 Feb 2021 18:57:14
User entered 'No (N)'	Christie Lyn Costanza (b) (4)	14 Jan 2021 19:35:53

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:35:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Nutritional Supplement'	Christie Lyn Costanza	14 Jan 2021 19:35:53
	(b) (4)	

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:35:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '50000'	Christie Lyn Costanza	14 Jan 2021 19:35:53
	(b) (4)	



US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:35:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'IU (IU)'	Christie Lyn Costanza	14 Jan 2021 19:35:53
	(b) (4)	

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:35:38**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered empty.	Christie Lyn Costanza	14 Jan 2021 19:35:53
	(b) (4)	

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:35:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'as needed (PRN)'	Christie Lyn Costanza	14 Jan 2021 19:35:53
	(b) (4)	

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:35:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered empty.	Christie Lyn Costanza	14 Jan 2021 19:35:53
	(b) (4)	

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:35:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Oral (ORAL)'	Christie Lyn Costanza	14 Jan 2021 19:35:53
	(b) (4)	

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:35:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered empty.	Christie Lyn Costanza	14 Jan 2021 19:35:53
	(b) (4)	

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:35:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'un Sep 2020'	Christie Lyn Costanza	14 Jan 2021 19:35:53
	(b) (4)	

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:35:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered '0'	Christie Lyn Costanza	14 Jan 2021 19:35:53
	(b) (4)	



US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:35:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'Yes (Y)'	Christie Lyn Costanza	14 Jan 2021 19:35:53
	(b) (4)	

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:35:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered empty.	Christie Lyn Costanza	14 Jan 2021 19:35:53
	(b) (4)	

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:35:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
	(b) (4)	
User entered 'No (N)'	Christie Lyn Costanza	14 Jan 2021 19:35:53
	(b) (4)	

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:35:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Jan 2021 19:35:53

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:35:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Jan 2021 19:35:53

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:35:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Jan 2021 19:35:53

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:35:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 07:01:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 07:01:30
User signature succeeded.	Shobha Swaminathan (b) (4)	23 Mar 2021 15:56:39
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, ATC: OTHER MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 09:43:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 09:43:43
Data point term sent to Coder	System	09 Mar 2021 22:19:23
User entered 'Botox injections'	Mario Portilla (b) (4) (b) (4)	09 Mar 2021 22:18:59

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:35:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	28 Apr 2021 10:36:50
User closed query 'Per DM CLR: Prophylaxis=Yes. Please review if this indication should be changed to MH as there is an MH recorded that matches this medication and used within the same timeframe. If yes, please update this field to No as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 14:33:26
Query 'Per DM CLR: Prophylaxis=Yes. Please review if this indication should be changed to MH as there is an MH recorded that matches this medication and used within the same timeframe. If yes, please update this field to No as appropriate. ' answered with 'per query, information has been updated' (Site from DM).	Mario Portilla (b) (4) (b) (4)	25 Mar 2021 21:58:14
Signature has been broken.	Mario Portilla (b) (4) (b) (4)	25 Mar 2021 21:57:16
User entered 'No (N)' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	25 Mar 2021 21:57:16
User opened query 'Per DM CLR: Prophylaxis=Yes. Please review if this indication should be changed to MH as there is an MH recorded that matches this medication and used within the same timeframe. If yes, please update this field to No as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 07:21:44
User signature succeeded.	Shobha Swaminathan (b) (4)	23 Mar 2021 15:56:39
User entered 'Yes (Y)'	Mario Portilla (b) (4) (b) (4)	09 Mar 2021 22:18:59



US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:35:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:56:39
	(b) (4)	
User entered 'Neuropathy, face (right side)'	Mario Portilla (b) (4)	09 Mar 2021 22:18:59
	(b) (4)	

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:35:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:56:39
	(b) (4)	
User entered 'unknown'	Mario Portilla (b) (4)	09 Mar 2021 22:18:59
	(b) (4)	

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:35:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:56:39
	(b) (4)	
User entered 'Other (OTHER)'	Mario Portilla (b) (4)	09 Mar 2021 22:18:59
	(b) (4)	

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:35:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:56:39
	(b) (4)	
User entered 'unknown'	Mario Portilla (b) (4)	09 Mar 2021 22:18:59
	(b) (4)	

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:35:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:56:39
	(b) (4)	
User entered 'other (OTHER)'	Mario Portilla (b) (4)	09 Mar 2021 22:18:59
	(b) (4)	

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:35:38

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:56:39
	(b) (4)	
User entered 'every 90 days'	Mario Portilla (b) (4)	09 Mar 2021 22:18:59
	(b) (4)	

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:35:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:56:39
	(b) (4)	
User entered 'Other (OTHER)'	Mario Portilla (b) (4)	09 Mar 2021 22:18:59
	(b) (4)	

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:35:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:56:39
	(b) (4)	
User entered 'intradermal'	Mario Portilla (b) (4)	09 Mar 2021 22:18:59
	(b) (4)	



US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:35:38

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:56:39
	(b) (4)	
User entered 'un UNK 2019'	Mario Portilla (b) (4)	09 Mar 2021 22:18:59
	(b) (4)	

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:35:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:56:39
	(b) (4)	
User entered '0'	Mario Portilla (b) (4)	09 Mar 2021 22:18:59
	(b) (4)	

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:35:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:56:39
	(b) (4)	
User entered 'Yes (Y)'	Mario Portilla (b) (4)	09 Mar 2021 22:18:59
	(b) (4)	

US3842060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:35:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:56:39
	(b) (4)	
User entered empty.	Mario Portilla (b) (4)	09 Mar 2021 22:18:59
	(b) (4)	

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:35:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:56:39
	(b) (4)	
User entered 'No (N)'	Mario Portilla (b) (4)	09 Mar 2021 22:18:59
	(b) (4)	

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:35:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 22:18:59

**US3842060**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:35:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 22:18:59

US3842060

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:35:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 22:18:59



US3842060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 12 Aug 2021 13:35:38

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:51:18
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:56:39
Signature has been broken.	(b) (4)	09 Mar 2021 22:37:29
	Mario Portilla (b) (4)	
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Mario Portilla (b) (4)	09 Mar 2021 22:37:29
	(b) (4)	
User signature succeeded.	Shobha Swaminathan	06 Mar 2021 00:08:05
	(b) (4)	
User entered 'No (N)'	Malithi Desilva (b) (4)	04 Mar 2021 22:14:53
	(b) (4)	

US3842060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 12 Aug 2021 13:35:38

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:56:39
	(b) (4)	
User entered '13 Jan 2021'	Mario Portilla (b) (4)	09 Mar 2021 22:39:49
	(b) (4)	

US3842060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 12 Aug 2021 13:35:38

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:56:39
	(b) (4)	
User entered 'Botox administration to face every 90 days'	Mario Portilla (b) (4)	09 Mar 2021 22:39:49
	(b) (4)	

US3842060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 12 Aug 2021 13:35:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:56:39
	(b) (4)	
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	09 Mar 2021 22:40:18
User entered 'Other (OTHER)' reason for change: Data Entry Error	Mario Portilla (b) (4)	09 Mar 2021 22:40:18
	(b) (4)	
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	09 Mar 2021 22:39:49
User entered 'Medical History (MH)'	Mario Portilla (b) (4)	09 Mar 2021 22:39:49
	(b) (4)	

US3842060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 12 Aug 2021 13:35:38

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Shobha Swaminathan	23 Mar 2021 15:56:39
	(b) (4)	
User entered 'neuropathy, right side of face'	Mario Portilla (b) (4)	09 Mar 2021 22:39:49
	(b) (4)	

US3842060

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:35:38

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:17:11
User closed query 'This page is applicable to Part A ONLY. The subject did not have 2 doses, thus discontinued dosing. Please complete page.' (Site from CRA).	(b) (4), (b) (6)	26 Mar 2021 21:27:24
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
Query 'This page is applicable to Part A ONLY. The subject did not have 2 doses, thus discontinued dosing. Please complete page.' answered with 'completed page with previous data per query ' (Site from CRA).	(b) (4) Malithi Desilva (b) (4)	26 Jan 2021 19:32:53
User entered '21 Oct 2020' reason for change: Per Query Resolution	(b) (4)	26 Jan 2021 19:32:34
User opened query 'This page is applicable to Part A ONLY. The subject did not have 2 doses, thus discontinued dosing. Please complete page.' (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 16:22:34
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	22 Jan 2021 07:11:54
Query 'Data is required. Please complete.' answered with 'pt no longer discontinued from treatment per amendment 6' (Site from System).	Christie Lyn Costanza (b) (4)	21 Jan 2021 00:15:38
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Jan 2021 00:15:23
User entered empty; reason for change Per Query Resolution	Christie Lyn Costanza (b) (4)	21 Jan 2021 00:15:23
User closed query 'Per CDM RQ: Site response noted. Please verify and correct the Date of dosing discontinuation of Investigational product appropriately. Thankyou.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 10:04:33
Query 'Per CDM RQ: Site response noted. Please verify and correct the Date of dosing discontinuation of Investigational product appropriately. Thankyou.' answered with 'participant received first injection on 21OCT2020, notified research team of exposure and positive saliva test on 26OCT2020.	Malithi Desilva (b) (4) (b) (4)	04 Dec 2020 16:02:52
Updated date of discontinuation to date of last exposure to investigational product per query. ' (Site from DM).		

US3842060

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:35:38

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '21 Oct 2020' reason for change: Per Query Resolution	Malithi Desilva (b) (4)	04 Dec 2020 16:02:48
User opened query 'Per CDM RQ: Site response noted. Please verify and correct the Date of dosing discontinuation of Investigational product appropriately. Thankyou.' (Site from DM).	(b) (4)	
User closed query 'Per CDM re-query: Site response is noted; however, Visit 1 Day 1 Exposure was on 21Oct2020. Please confirm and update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 11:09:28
Query 'Per CDM re-query: Site response is noted; however, Visit 1 Day 1 Exposure was on 21Oct2020. Please confirm and update accordingly. Thank you.' answered with 'please clarify "date of last exposure" exposure to COVID19? or exposure to investigational product?' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 11:09:28
User opened query 'Per CDM re-query: Site response is noted; however, Visit 1 Day 1 Exposure was on 21Oct2020. Please confirm and update accordingly. Thank you.' (Site from DM).	Malithi Desilva (b) (4)	30 Nov 2020 18:41:32
User closed query 'Per CDM: Per pages 38-39 of CCGs version 2.0, "Date of dosing discontinuation" should be the same as date of last exposure. Thank you.' (Site from DM).	(b) (4)	
Query 'Per CDM: Per pages 38-39 of CCGs version 2.0, "Date of dosing discontinuation" should be the same as date of last exposure. Thank you.' answered with 'The participant reported testing positive on a saliva test conducted in the workplace on 26OCT2020' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 14:10:00
User entered '26 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 14:10:00
User opened query 'Per CDM: Per pages 38-39 of CCGs version 2.0, "Date of dosing discontinuation" should be the same as date of last exposure. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 18:04:13
User entered '18 Nov 2020'	Zoraida Cruz (b) (4)	23 Nov 2020 18:02:57
	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 15:00:07
	Mario Portilla (b) (4)	18 Nov 2020 20:02:07
	(b) (4)	

US3842060

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:35:38

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:17:11
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered 'Due to SARS-COV-2 (COVID)' reason for change: Per Query Resolution	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	Malithi Desilva (b) (4)	26 Jan 2021 19:32:34
Query 'Data is required. Please complete.' answered with 'pt no longer discontinued from treatment per amendment 6' (Site from System).	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	22 Jan 2021 07:11:56
User entered empty; reason for change Data Entry Error	Christie Lyn Costanza	21 Jan 2021 00:15:41
User entered 'Due to SARS-COV-2 (COVID)' reason for change: Data Entry Error	(b) (4)	
User entered 'Other (OTHER)'	System	21 Jan 2021 00:15:23
	Christie Lyn Costanza	21 Jan 2021 00:15:23
	(b) (4)	
	Zoraida Cruz (b) (4)	23 Nov 2020 18:04:51
	(b) (4)	
	Mario Portilla (b) (4)	18 Nov 2020 20:02:07
	(b) (4)	



US3842060

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:35:38

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:17:11
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User closed query 'Per CDM: Per CCGs pages 38-39 of CCGs version 2.0 (enter due to SARS-COV-2 if participant is diagnosed). Please confirm if patient was diagnosed. Also complete the Covid-19 Assessment and AE pages. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:03:52
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	23 Nov 2020 18:07:18
User entered empty; reason for change Per Query Resolution	Zoraida Cruz (b) (4) (b) (4)	23 Nov 2020 18:07:18
Query 'Per CDM: Per CCGs pages 38-39 of CCGs version 2.0 (enter due to SARS-COV-2 if participant is diagnosed). Please confirm if patient was diagnosed. Also complete the Covid-19 Assessment and AE pages. Thank you. ' answered with 'The participant self-reported testing positive on 26OCT2020' (Site from DM).	Zoraida Cruz (b) (4) (b) (4)	23 Nov 2020 18:06:48
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	23 Nov 2020 18:04:51
User opened query 'Per CDM: Per CCGs pages 38-39 of CCGs version 2.0 (enter due to SARS-COV-2 if participant is diagnosed). Please confirm if patient was diagnosed. Also complete the Covid-19 Assessment and AE pages. Thank you. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 14:59:47
User entered 'Protocol directive via ePIP has requested that 2nd dose not be administered. Participant had a positive saliva test that was administered at his worksite.'	Mario Portilla (b) (4) (b) (4)	18 Nov 2020 20:02:07

US3842060

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:35:38

Date of study discontinuation/completion (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:17:11
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User closed query 'Per CDM: Site response noted. Since participant will continue in the study, please remove all data on this page. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 14:10:26
Query 'Per CDM: Site response noted. Since participant will continue in the study, please remove all data on this page. Thank you.' answered with 'updated.' (Site from DM).	Zoraida Cruz (b) (4) (b) (4)	23 Nov 2020 19:16:28
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	20 Nov 2020 14:57:07
User opened query 'Per CDM: Site response noted. Since participant will continue in the study, please remove all data on this page. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 14:57:06
Query 'Data is required. Please complete.' answered with 'data entry error, participant consented to continue study without receiving second dose of injection' (Site from System).	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:18:18
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 20:17:33
User entered empty; reason for change New Information	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:17:33
User entered '18 Nov 2020'	Mario Portilla (b) (4) (b) (4)	18 Nov 2020 20:03:46

US3842060

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:35:38

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:17:11
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty; reason for change Data Entry Error	(b) (4) Zoraida Cruz (b) (4)	23 Nov 2020 19:16:13
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 14:57:09
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	Mario Portilla (b) (4) (b) (4)	18 Nov 2020 20:39:09
Query 'Data is required. Please complete.' answered with 'data entry error, participant consented to continue study without receiving second dose of injection' (Site from System).	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:18:20
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 20:17:33
User entered empty; reason for change Data Entry Error	Malithi Desilva (b) (4) (b) (4)	18 Nov 2020 20:17:33
User entered 'Study Terminated By Sponsor (STUDY TERMINATED BY SPONSOR)'	Mario Portilla (b) (4) (b) (4)	18 Nov 2020 20:03:46

US3842060

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:35:38

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:17:11
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty; reason for change Per Query Resolution	(b) (4) Zoraida Cruz (b) (4)	23 Nov 2020 19:16:13
User entered 'protocol deviation' reason for change: Per Query Resolution	(b) (4) Mario Portilla (b) (4)	18 Nov 2020 20:39:09
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	(b) (4) System	18 Nov 2020 20:17:33
User entered empty; reason for change Per Query Resolution	Malithi Desilva (b) (4)	18 Nov 2020 20:17:33
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	(b) (4) System	18 Nov 2020 20:06:03
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	18 Nov 2020 20:06:03
User entered 'Positive saliva test. SALIVA WORK AFTER 1ST ADMINISTRATION. EPIP RESPONSE DIRECTED THAT 2ND DOSE NOT BE ADMINISTERED' reason for change: Per Query Resolution	Mario Portilla (b) (4)	18 Nov 2020 20:06:03
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	(b) (4) System	18 Nov 2020 20:04:52
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	18 Nov 2020 20:04:52

US3842060

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:35:38

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User entered 'PARTICIPANT HAD A POSITIVE SALIVA TEST AT WORK AFTER 1ST ADMINISTRATION. EPIP response directed that 2nd dose not be administered' reason for change: Per Query Resolution	Mario Portilla (b) (4) (b) (4)	18 Nov 2020 20:04:52
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	18 Nov 2020 20:03:46
User entered 'participant had a positive saliva test at work after 1st administration'	Mario Portilla (b) (4) (b) (4)	18 Nov 2020 20:03:46

US3842060

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:35:38

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:17:11
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4)	18 Nov 2020 20:03:46
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:35:38

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:17:11
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4)	18 Nov 2020 20:03:46
	Mario Portilla (b) (4)	
	(b) (4)	

US3842060

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:35:38

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:17:11
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4)	18 Nov 2020 20:03:46
	Mario Portilla (b) (4)	
	(b) (4)	



US3842060

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:35:38

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:17:11
User signature succeeded.	Shobha Swaminathan	16 Feb 2021 18:57:14
User entered empty.	(b) (4)	18 Nov 2020 20:03:46
	Mario Portilla (b) (4)	
	(b) (4)	