

US3002122 (Prod: Meridian Clinical Research)

Generated By: KC Joubran

Generated On: 11 Aug 2021 21:50:29

All time stamps listed in this document are displayed in GMT

US3002122

Form: Participant Creation

Data signed: (b) (4) 13 Feb 2021 13:00:52

Generated On: 11 Aug 2021 21:50:29

---

[Participant ID](#)

US3002122

---

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

---

---

US3002122

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 13:00:53

Generated On: 11 Aug 2021 21:50:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3002122

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 13:00:53

Generated On: 11 Aug 2021 21:50:29

Date of Birth (MMM yyyy)	(b) (6) 1995
Age	25
Age Units	YEARS
Age (Derived)	25
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3002122

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 13:00:53

Generated On: 11 Aug 2021 21:50:29

Date of Informed Consent ( <i>dd MMM yyyy</i> )	07 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3002122

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 13:00:53

Generated On: 11 Aug 2021 21:50:29

---

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

---

US3002122

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 13:00:53

Generated On: 11 Aug 2021 21:50:29

---

Were any significant conditions reported?

Yes ☒  
No ☐

---

US3002122

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 13:00:53

Generated On: 11 Aug 2021 21:50:29

Condition	INTERMITTENT HEADACHE
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)	



US3002122

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 13:00:53

Generated On: 11 Aug 2021 21:50:29

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

US3002122

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 13:00:53

Generated On: 11 Aug 2021 21:50:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 AUG 2020
Time of assessment (00:00-23:59)	07:16 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 07:16
Height (xxx.x)	167 cm
Weight (xxx.x)	73.6 kg
BMI (xxx.x)	26.39033 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3002122

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 13:00:53

Generated On: 11 Aug 2021 21:50:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 AUG 2020

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

US3002122

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 13 Feb 2021 13:00:53

Generated On: 11 Aug 2021 21:50:29

Date of assessment (*dd MMM yyyy*) 07 AUG 2020

Is the participant of childbearing potential? Yes ☒  
No ☐

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

If Partner medically sterile or Other, specify \_\_\_\_\_  
If Surgically sterile, date of surgery (*dd MMM yyyy*) \_\_\_\_\_  
Date of surgery unknown False  
If Post-menopausal, date of last menstruation (*dd MMM yyyy*) \_\_\_\_\_  
Date of last menstruation unknown False

US3002122

Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 13 Feb 2021 13:00:53

Generated On: 11 Aug 2021 21:50:29

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	07 AUG 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3002122

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 13:00:53

Generated On: 11 Aug 2021 21:50:29

---

**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**

LAB TECHNICIAN

---

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

**No Risk Identified** False

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

US3002122

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 13:00:53

Generated On: 11 Aug 2021 21:50:29

<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>	

US3002122

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 13:01:05

Generated On: 11 Aug 2021 21:50:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1



US3002122

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 13:00:53

Generated On: 11 Aug 2021 21:50:29

What was the date of randomization? (dd MMM yyyy) 07 AUG 2020

What was the participant's randomization number? 101751

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 ☒

US3002122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 13:01:05

Generated On: 11 Aug 2021 21:50:29

Height	ND - Not Done
Weight	ND - Not Done

US3002122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 13:01:05

Generated On: 11 Aug 2021 21:50:29

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 AUG 2020
Time of assessment (00:00-23:59)	07:16 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 07:16
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3002122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 13:01:05

Generated On: 11 Aug 2021 21:50:29

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	07 AUG 2020
Time of assessment (00:00-23:59)	08:35 (24 HR)
Vital Signs Date and Time (derived)	07 AUG 2020 08:35
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3002122

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 13:00:53

Generated On: 11 Aug 2021 21:50:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 AUG 2020

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

US3002122

Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 13 Feb 2021 13:00:53

Generated On: 11 Aug 2021 21:50:29

Was the pregnancy test performed? Yes ☐  
No ☒

Date of test (dd MMM yyyy) \_\_\_\_\_

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☒

Collection date \_\_\_\_\_

Collection time \_\_\_\_\_

Collection date and time (derived) \_\_\_\_\_

US3002122

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 13:00:53

Generated On: 11 Aug 2021 21:50:29

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) 07 AUG 2020

What was the treatment time? (00:00-23:59) 08:04 (24 HR)

Treatment Date and Time (derived) 07 AUG 2020 08:04

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

What was the frequency of the study treatment dosing? ONCE

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

US3002122

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 13:00:53

Generated On: 11 Aug 2021 21:50:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	07 AUG 2020
Collection time (00:00-23:59)	07:35 (24 HR)
Collection date and time (derived)	07 AUG 2020 07:35



US3002122

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 13:00:53

Generated On: 11 Aug 2021 21:50:29

Collection date (dd MMM yyyy)			07 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	07:36	07 AUG 2020 07:36
Nasopharyngeal Swab 2	No		

US3002122

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 13:00:53

Generated On: 11 Aug 2021 21:50:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002122

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐  
No ☒

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

PC Time Stamp 07 AUG 2020 08:35

PC Open Date & Time 07 AUG 2020 08:24

PC Close Date & Time 07 AUG 2020 10:54

US3002122

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

**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 98.2 °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	07 AUG 2020 11:53
PC Open Date & Time	07 AUG 2020 11:49
PC Close Date & Time	08 AUG 2020 11:59

US3002122

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:50:29

**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

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

08 AUG 2020 12:16

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3002122

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 12:02

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3002122

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:50:29

---

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 13:45

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3002122

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

11 AUG 2020 12:01

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59



US3002122

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 13:58

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3002122

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:50:29

---

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

13 AUG 2020 13:58

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

07 AUG 2020 08:35

PC Open Date & Time

07 AUG 2020 08:24

PC Close Date & Time

07 AUG 2020 10:54

US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

**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

07 AUG 2020 11:50

PC Open Date & Time

07 AUG 2020 11:49

PC Close Date & Time

08 AUG 2020 11:59

US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:50:29

**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

08 AUG 2020 12:16

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:50:29

**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

09 AUG 2020 12:01

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:50:29

**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

10 AUG 2020 13:45

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:50:29

**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

11 AUG 2020 12:01

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59



US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:50:29

**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

12 AUG 2020 13:57

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:50:29

**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

13 AUG 2020 13:58

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3002122

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

**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 ☐

US3002122

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 08:36
PC Open Date & Time	07 AUG 2020 08:24
PC Close Date & Time	07 AUG 2020 10:54

US3002122

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

**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 ☐

US3002122

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 11:50
PC Open Date & Time	07 AUG 2020 11:49
PC Close Date & Time	08 AUG 2020 11:59

US3002122

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:50:29

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 1720

EAB) (1725)

US3002122

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:50:29

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 12:16
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59



US3002122

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:50:29

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 ☒

US3002122

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:50:29

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 12:01
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3002122

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:50:29

**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 ☒

US3002122

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:50:29

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 13:44
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3002122

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:50:29

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 ☒

US3002122

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:50:29

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

US3002122

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:50:29

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 ☒

US3002122

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:50:29

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 13:57
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59



US3002122

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:50:29

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

56 of 1720

EAB) (1725)

US3002122

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:50:29

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 13:58
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3002122

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 13:00:53

Generated On: 11 Aug 2021 21:50:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3002122

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 13:00:53

Generated On: 11 Aug 2021 21:50:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002122

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 13:00:53

Generated On: 11 Aug 2021 21:50:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3002122

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 13:00:53

Generated On: 11 Aug 2021 21:50:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002122

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 13:00:53

Generated On: 11 Aug 2021 21:50:29

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3002122

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 13:00:53

Generated On: 11 Aug 2021 21:50:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3002122

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 13:01:05

Generated On: 11 Aug 2021 21:50:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3002122

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 13:01:05

Generated On: 11 Aug 2021 21:50:29

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)	04 SEP 2020
Time of assessment (00:00-23:59)	08:38 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 08:38
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3002122

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 13:01:05

Generated On: 11 Aug 2021 21:50:29

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)	04 SEP 2020
Time of assessment (00:00-23:59)	09:56 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 09:56
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3002122

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 13:01:05

Generated On: 11 Aug 2021 21:50:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 SEP 2020

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

US3002122

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 13 Feb 2021 13:01:05

Generated On: 11 Aug 2021 21:50:29

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	04 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3002122

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 13:01:05

Generated On: 11 Aug 2021 21:50:29

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) 04 SEP 2020

What was the treatment time? (00:00-23:59) 09:22 (24 HR)

Treatment Date and Time (derived) 04 SEP 2020 09:22

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

What was the frequency of the study treatment dosing? ONCE

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

US3002122

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 13:01:05

Generated On: 11 Aug 2021 21:50:29

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

04 SEP 2020

Collection time (00:00-23:59)

08:57 (24 HR)

Collection date and time (derived)

04 SEP 2020 08:57

US3002122

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 13:01:05

Generated On: 11 Aug 2021 21:50:29

Collection date (dd MMM yyyy)			04 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:48	04 SEP 2020 08:48
Nasopharyngeal Swab 2	No		



US3002122

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 13:01:05

Generated On: 11 Aug 2021 21:50:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002122

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 09:48

PC Open Date & Time

04 SEP 2020 09:42

PC Close Date & Time

04 SEP 2020 12:12

US3002122

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

**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 98.3 °F

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

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

PC Time Stamp	05 SEP 2020 11:50
PC Open Date & Time	04 SEP 2020 13:07
PC Close Date & Time	05 SEP 2020 11:59

US3002122

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:50:29

---

**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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 12:09

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3002122

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:50:29

**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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 09:44

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3002122

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

07 SEP 2020 18:13

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3002122

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

08 SEP 2020 17:33

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3002122

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 12:00

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59



US3002122

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 12:31

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

**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

04 SEP 2020 09:48

PC Open Date & Time

04 SEP 2020 09:42

PC Close Date & Time

04 SEP 2020 12:12

US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

**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

05 SEP 2020 11:50

PC Open Date & Time

04 SEP 2020 13:07

PC Close Date & Time

05 SEP 2020 11:59

US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:50:29

**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

05 SEP 2020 12:09

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:50:29

**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

06 SEP 2020 12:01

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:50:29

**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

07 SEP 2020 14:28

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 17:30

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:50:29

**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

09 SEP 2020 12:00

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59



US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:50:29

**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

10 SEP 2020 12:31

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3002122

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

**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 ☐

US3002122

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 09:49
PC Open Date & Time	04 SEP 2020 09:42
PC Close Date & Time	04 SEP 2020 12:12

US3002122

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

**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 ☐

US3002122

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

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

No ☒

Yes ☐

PC Time stamp	05 SEP 2020 11:50
PC Open Date & Time	04 SEP 2020 13:07
PC Close Date & Time	05 SEP 2020 11:59

US3002122

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:50:29

**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 ☒

US3002122

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:50:29

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 12:09
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3002122

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:50:29

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 ☒



US3002122

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:50:29

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 12:05
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3002122

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:50:29

**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 ☒

US3002122

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:50:29

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 14:29
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3002122

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:50:29

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

99 of 1720

EAB) (1725)

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:50:29**

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 17:31
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3002122

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:50:29

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 ☒

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:50:29**

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 12:01
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3002122

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:50:29

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

103 of 1720

EAB) (1725)



**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:50:29**

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 12:31
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3002122

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 13:00:53

Generated On: 11 Aug 2021 21:50:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3002122

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 13:00:53

Generated On: 11 Aug 2021 21:50:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002122

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 13:00:53

Generated On: 11 Aug 2021 21:50:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3002122

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 13:00:53

Generated On: 11 Aug 2021 21:50:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002122

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 13:00:53

Generated On: 11 Aug 2021 21:50:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3002122

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 13:00:53

Generated On: 11 Aug 2021 21:50:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002122

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 13:01:05

Generated On: 11 Aug 2021 21:50:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3



US3002122

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 13:01:05

Generated On: 11 Aug 2021 21:50:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 SEP 2020
Time of assessment (00:00-23:59)	08:03 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 08:03
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3002122

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 13:01:05

Generated On: 11 Aug 2021 21:50:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 SEP 2020

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

US3002122

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 13:01:05

Generated On: 11 Aug 2021 21:50:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 SEP 2020
Collection time (00:00-23:59)	08:25 (24 HR)
Collection date and time (derived)	30 SEP 2020 08:25

US3002122

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 13:01:05

Generated On: 11 Aug 2021 21:50:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002122

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 OCT 2020 20:54:41
Patient Cloud Open Date & Time	07 OCT 2020 00:01
Patient Cloud Close Date & Time	11 OCT 2020 23:59

US3002122

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 OCT 2020 14:46:08

Patient Cloud Open Date & Time

14 OCT 2020 00:01

Patient Cloud Close Date & Time

18 OCT 2020 23:59

US3002122

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 OCT 2020 04:57:14
Patient Cloud Open Date & Time	21 OCT 2020 00:01
Patient Cloud Close Date & Time	25 OCT 2020 23:59

US3002122

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 NOV 2020 11:08:58

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59



US3002122

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 01:37:51

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3002122

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 04:19:23

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	22 NOV 2020 19:05:56
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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 type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	29 NOV 2020 06:40:40
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 DEC 2020 21:20:43

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

13 DEC 2020 08:39:12

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

20 DEC 2020 19:40:05

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 08:11:19

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59



US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

04 JAN 2021 13:12:57

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 JAN 2021 09:06:46
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

<b>TIMEPOINT</b>	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 JAN 2021 15:32:05
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

24 JAN 2021 07:34:48

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 JAN 2021 06:37:54
Patient Cloud Open Date & Time	31 JAN 2021 00:01
Patient Cloud Close Date & Time	04 FEB 2021 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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

07 FEB 2021 13:48:41

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 FEB 2021 06:24:19
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 06:54:43

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59



US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 08:11:29

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 MAR 2021 06:16:49

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 MAR 2021 08:45:00

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 09:49:55

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

<b>TIMEPOINT</b>	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	29 MAR 2021 06:10:16
Patient Cloud Open Date & Time	28 MAR 2021 00:01
Patient Cloud Close Date & Time	01 APR 2021 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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 ☐

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

[Patient Cloud Close Date & Time](#)

08 APR 2021 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 07:41:19

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59



US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 14:56:07

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 20:48:47

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 09:21:58

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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 ☐

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 285

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

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

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

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

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

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

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

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

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°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"/>



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

[Patient Cloud Close Date & Time](#)

---

27 MAY 2021 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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 ☐

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

06 JUN 2021 00:01

---

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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 <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"/>

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

20 JUN 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

24 JUN 2021 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

27 JUN 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

01 JUL 2021 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

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

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

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	11 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 JUL 2021 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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"/>



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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 <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"/>

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

01 AUG 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

05 AUG 2021 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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 <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"/>

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

[Patient Cloud Close Date & Time](#)

---

12 AUG 2021 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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 <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"/>

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

[Patient Cloud Close Date & Time](#)

---

02 SEP 2021 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

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

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

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 404

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

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

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

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

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

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

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

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



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	26 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 SEP 2021 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

03 OCT 2021 00:01

---

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Please contact your study clinic immediately. Click below to confirm that you have read this 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](#)

10 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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"/>

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 OCT 2021 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	24 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 OCT 2021 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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°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 ☐

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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"/>



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

[Patient Cloud Close Date & Time](#)

---

11 NOV 2021 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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="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"/>

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

14 NOV 2021 00:01

---

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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 <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"/>

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

[Patient Cloud Close Date & Time](#)

---

25 NOV 2021 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 481

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

[Patient Cloud Close Date & Time](#)

---

02 DEC 2021 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 488

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

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

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

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

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

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

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

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



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

[Patient Cloud Close Date & Time](#)

---

09 DEC 2021 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 DEC 2021 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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 ☐

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	19 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	23 DEC 2021 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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 ☐

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	26 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 DEC 2021 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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 ☐

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

[Patient Cloud Close Date & Time](#)

---

20 JAN 2022 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

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

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

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

[Patient Cloud Close Date & Time](#)

---

27 JAN 2022 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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 ☐



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

30 JAN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

03 FEB 2022 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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°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 ☐

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

06 FEB 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

10 FEB 2022 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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 ☐

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

13 FEB 2022 00:01

---

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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 ☐

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

20 FEB 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

24 FEB 2022 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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 ☐



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

27 FEB 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

03 MAR 2022 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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 ☐

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

06 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

10 MAR 2022 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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 ☐

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

13 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

17 MAR 2022 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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 ☐

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

20 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

24 MAR 2022 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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="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"/>



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

27 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

31 MAR 2022 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 607

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

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

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

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

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

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

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

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

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

03 APR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

07 APR 2022 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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°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"/>

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 APR 2022 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

[Patient Cloud Close Date & Time](#)

---

21 APR 2022 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

[Patient Cloud Close Date & Time](#)

---

28 APR 2022 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

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

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

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

01 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

05 MAY 2022 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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="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"/>

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

15 MAY 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

19 MAY 2022 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

[Patient Cloud Close Date & Time](#)

---

26 MAY 2022 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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 <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"/>

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

[Patient Cloud Close Date & Time](#)

---

02 JUN 2022 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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="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"/>

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

[Patient Cloud Close Date & Time](#)

---

09 JUN 2022 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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 ☐

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

12 JUN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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 ☐



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°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"/>

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

26 JUN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

30 JUN 2022 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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 ☐

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

03 JUL 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

07 JUL 2022 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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 ☐

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

[Patient Cloud Close Date & Time](#)

---

14 JUL 2022 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 JUL 2022 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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"/>

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

[Patient Cloud Close Date & Time](#)

---

28 JUL 2022 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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"/>

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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"/>



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

14 AUG 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

18 AUG 2022 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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 <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"/>

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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"/>

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

[Patient Cloud Close Date & Time](#)

---

08 SEP 2022 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

DAY 768

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

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

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

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

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

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

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

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



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

[Patient Cloud Close Date & Time](#)

---

15 SEP 2022 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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 ☐

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

[Patient Cloud Close Date & Time](#)

---

22 SEP 2022 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

**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 ☐

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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 <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"/>

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

---

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

---

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

---

**US3002122**

**Folder: Cosmetic Injections and Dermal Fillers**

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

**Generated On: 11 Aug 2021 21:50:29**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 08:11:41

US3002122

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 13:00:53

Generated On: 11 Aug 2021 21:50:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3002122

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 13:00:53

Generated On: 11 Aug 2021 21:50:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002122

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 13:00:52

Generated On: 11 Aug 2021 21:50:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3002122

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 13:00:52

Generated On: 11 Aug 2021 21:50:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002122

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 13:00:52

Generated On: 11 Aug 2021 21:50:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3002122

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 13:00:52

Generated On: 11 Aug 2021 21:50:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3002122

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Mar 2021 12:43:25

Generated On: 11 Aug 2021 21:50:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3002122

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Mar 2021 12:43:25

Generated On: 11 Aug 2021 21:50:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3002122

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 29 Mar 2021 04:42:06

Generated On: 11 Aug 2021 21:50:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>
Folder OID	VISIT4

US3002122

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 01 Apr 2021 19:07:27

Generated On: 11 Aug 2021 21:50:29

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3002122

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 19:07:27

Generated On: 11 Aug 2021 21:50:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 FEB 2021

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

US3002122

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 01 Apr 2021 19:07:27

Generated On: 11 Aug 2021 21:50:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	18 FEB 2021
-------------------------------	-------------

Collection time (00:00-23:59)	14:56 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	18 FEB 2021 14:56
------------------------------------	-------------------

US3002122

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 19:07:27

Generated On: 11 Aug 2021 21:50:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3002122**

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

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:50:29**

Was Contact Attempted? Yes ☐  
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



**US3002122**

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

**Form: Continuing**

**Generated On: 11 Aug 2021 21:50:29**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3002122**

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

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 21:50:29**

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

**US3002122**

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

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

**Generated On: 11 Aug 2021 21:50:29**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3002122

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

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 12:40:07

Generated On: 11 Aug 2021 21:50:29

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

Visit date (dd MMM yyyy)	18 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	UNBLND_DECIDE
------------	---------------

US3002122

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

Form: Unblinding

Data signed: (b) (4) 25 Mar 2021 12:40:07

Generated On: 11 Aug 2021 21:50:29

Date of updated informed consent ( <i>dd MMM yyyy</i> )	18 FEB 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> )	18 FEB 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	

US3002122

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 12:40:07

Generated On: 11 Aug 2021 21:50:29

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

18 FEB 2021

Collection time (00:00-23:59)

14:56 (24 HR)

Collection date and time (derived)

18 FEB 2021 14:56

US3002122

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 25 Mar 2021 12:40:07

Generated On: 11 Aug 2021 21:50:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Collection date (dd MMM yyyy)	18 FEB 2021
-------------------------------	-------------

Collection time (00:00 - 23:59)	14:48
---------------------------------	-------

Collection Date and Time (derived)	18 FEB 2021 14:48
------------------------------------	-------------------

US3002122

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Feb 2021 13:00:52

Generated On: 11 Aug 2021 21:50:29

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---



US3002122

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 15:13:44

Generated On: 11 Aug 2021 21:50:29

AEID	
Adverse event	WEIGHT GAIN
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)	24 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input 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)

320 of 1720

US3002122

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 15:13:44

Generated On: 11 Aug 2021 21:50:29

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 checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3002122

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Apr 2021 15:13:44

Generated On: 11 Aug 2021 21:50:29

AEID	
Adverse event	MYALGIA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input 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)	29 AUG 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 AUG 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)

322 of 1720

US3002122

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Apr 2021 15:13:44

Generated On: 11 Aug 2021 21:50:29

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 type="radio"/> Related <input checked="" 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 _____	
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)	_____

US3002122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 13 Feb 2021 13:00:52

Generated On: 11 Aug 2021 21:50:29

---

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

Yes ☒

No ☐

---

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

---

US3002122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 13 Feb 2021 13:00:52

Generated On: 11 Aug 2021 21:50:29

Name of Medication ZOLOFT

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

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 1720

EAB) (1725)

US3002122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 13 Feb 2021 13:00:52

Generated On: 11 Aug 2021 21:50:29

	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 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3002122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 13 Feb 2021 13:00:52

Generated On: 11 Aug 2021 21:50:29

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication INTERMITTENT HEADACHES

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

327 of 1720

EAB) (1725)



US3002122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 13 Feb 2021 13:00:52

Generated On: 11 Aug 2021 21:50:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3002122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 13 Feb 2021 13:00:52

Generated On: 11 Aug 2021 21:50:29

Name of Medication PHENTERMINE

Prophylaxis Yes ☐  
No ☒

Indication WEIGHT GAIN

Dose per administration 37.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

329 of 1720

US3002122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 13 Feb 2021 13:00:52

Generated On: 11 Aug 2021 21:50:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3002122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 13 Feb 2021 13:00:52

Generated On: 11 Aug 2021 21:50:29

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication INFLUENZA PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

331 of 1720

US3002122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 13 Feb 2021 13:00:52

Generated On: 11 Aug 2021 21:50:29

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		24 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		24 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3002122

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 13 Feb 2021 13:00:52

Generated On: 11 Aug 2021 21:50:29

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3002122

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:50:29

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3002122

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:50:29

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

US3002122 (Prod: Meridian Clinical Research)

**US3002122**

**Form: Participant Creation**

**Generated On: 11 Aug 2021 21:50:29**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'US3002122'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 12:29:15

**US3002122**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:50:29**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:17:25

**US3002122**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:50:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '07 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 12:29:16

**US3002122**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:50:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:17:25

**US3002122**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:50:29**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User entered 'SCRN'	System	07 Aug 2020 15:17:25

US3002122

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:50:29

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered (b) (6) 1995'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 12:29:17

**US3002122**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:50:29**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '25'	(b) (4), (b) (6)	07 Aug 2020 15:17:42



**US3002122**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:50:29**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User entered 'YEARS'	System	07 Aug 2020 15:17:42

**US3002122**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:50:29**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User entered '25'	System	07 Aug 2020 13:09:21

**US3002122**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:50:29**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:17:42

**US3002122**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:50:29**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:17:42

**US3002122**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:50:29**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'I'	(b) (4), (b) (6)	07 Aug 2020 15:17:42

**US3002122**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:50:29**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 15:17:42

**US3002122**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:50:29**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 15:17:42

**US3002122**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:50:29**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:17:42



**US3002122**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:50:29**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:17:42

**US3002122**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:50:29**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 15:17:42

**US3002122**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:50:29**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 15:17:42

**US3002122**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:50:29**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 15:17:42

**US3002122**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:50:29**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 15:17:42

**US3002122**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:50:29**

**Date of Informed Consent** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '07 Aug 2020'	Jessica Satorie (b) (4)	07 Aug 2020 13:09:21

**US3002122**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:50:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User entered 'Aug 2020'	System	07 Aug 2020 13:09:21

**US3002122**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:50:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User entered '2020'	System	07 Aug 2020 13:09:21



**US3002122**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:50:29**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Amendment 1 (1)'	Jessica Satorie (b) (4)	07 Aug 2020 13:09:21

**US3002122**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:50:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	07 Aug 2020 13:09:21

**US3002122**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:50:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	Jessica Satorie (b) (4)	07 Aug 2020 13:09:21

**US3002122**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:50:29**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	Jessica Satorie (b) (4)	07 Aug 2020 13:09:21

**US3002122**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:50:29**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'No (N)'	Jessica Satorie (b) (4)	07 Aug 2020 13:09:21

**US3002122**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:50:29**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 12:29:16

**US3002122**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:50:29**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User entered 'I'	System	07 Aug 2020 13:09:28

**US3002122**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 11 Aug 2021 21:50:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	07 Aug 2020 13:09:28



**US3002122**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 11 Aug 2021 21:50:29**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:18:34

US3002122

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:50:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Intermittent headache - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 15:20:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 15:20:18
Data point term sent to Coder	System	07 Aug 2020 15:19:14
User entered 'Intermittent headache'	(b) (4), (b) (6)	07 Aug 2020 15:18:55

**US3002122**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:50:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'UN UNK 2010' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Oct 2020 14:02:40
User entered 'un UNK 2017'	(b) (4), (b) (6)	07 Aug 2020 15:18:55

**US3002122**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 15:18:55

**US3002122**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:18:55

**US3002122**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:50:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 15:18:55

**US3002122**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 15:18:55

**US3002122**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:50:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User entered 'Jan 2010'	System	02 Oct 2020 14:02:40
User entered 'Jan 2017'	System	07 Aug 2020 15:18:55



**US3002122**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:50:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User entered '2010'	System	02 Oct 2020 14:02:40
User entered '2017'	System	07 Aug 2020 15:18:55

**US3002122**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:50:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User entered empty.	System	07 Aug 2020 15:18:55

**US3002122**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:50:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User entered empty.	System	07 Aug 2020 15:18:55

US3002122

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:50:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 15:59:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 15:59:24
Data point term sent to Coder	System	10 Aug 2020 15:56:37
User entered 'Depression'	(b) (4), (b) (6)	10 Aug 2020 15:56:02

**US3002122**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:50:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'un UNK 2019'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:56:02

**US3002122**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '0'	(b) (4), (b) (6)	10 Aug 2020 15:56:02

**US3002122**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:56:02

**US3002122**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:50:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 15:56:02



**US3002122**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '0'	(b) (4), (b) (6)	10 Aug 2020 15:56:02

**US3002122**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:50:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User entered 'Jan 2019'	System	10 Aug 2020 15:56:02

**US3002122**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:50:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User entered '2019'	System	10 Aug 2020 15:56:02

**US3002122**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:50:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User entered empty.	System	10 Aug 2020 15:56:02

**US3002122**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:50:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User entered empty.	System	10 Aug 2020 15:56:02

**US3002122**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:19:53

**US3002122**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '07 Aug 2020'	(b) (4), (b) (6)	07 Aug 2020 15:19:53

**US3002122**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '07:16'	(b) (4), (b) (6)	07 Aug 2020 15:19:53



**US3002122**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User entered '07 Aug 2020 07:16'	System	07 Aug 2020 15:19:53

**US3002122**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '167' cm	(b) (4)	07 Aug 2020 15:19:53
DataPoint set to visible.	(b) (4), (b) (6)	07 Aug 2020 13:09:28
	System	

**US3002122**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '73.6' kg	(b) (4)	
	(b) (4), (b) (6)	07 Aug 2020 15:19:53
DataPoint set to visible.	System	07 Aug 2020 13:09:28

**US3002122**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
Amendment Manager: User entered '26.39033'	System	16 Sep 2020 23:46:47
User entered '26.4'	System	07 Aug 2020 15:19:53
DataPoint set to visible.	System	07 Aug 2020 13:09:28

**US3002122**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User entered 'kg/m2'	System	07 Aug 2020 15:19:53
DataPoint set to visible.	System	07 Aug 2020 13:09:28

**US3002122**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered missing code ND - Not Done; reason for	(b) (4)	04 Sep 2020 15:48:35
change Data Entry Error	(b) (4), (b) (6)	
User entered '36.7' C	(b) (4), (b) (6)	07 Aug 2020 15:19:53

**US3002122**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty; reason for change Data Entry Error	(b) (4)	04 Sep 2020 15:48:35
User entered 'Oral (Oral)'	(b) (4), (b) (6)	07 Aug 2020 15:19:53

**US3002122**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 15:19:53



**US3002122**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered missing code ND - Not Done; reason for	(b) (4)	04 Sep 2020 15:48:35
change Data Entry Error	(b) (4), (b) (6)	
User entered '66'	(b) (4), (b) (6)	07 Aug 2020 15:19:53

**US3002122**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User entered 'bpm'	System	07 Aug 2020 15:19:53

**US3002122**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered missing code ND - Not Done; reason for	(b) (4)	04 Sep 2020 15:48:35
change Data Entry Error	(b) (4), (b) (6)	
User entered '16'	(b) (4), (b) (6)	07 Aug 2020 15:19:53

**US3002122**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User entered 'breaths/min'	System	07 Aug 2020 15:19:53

**US3002122**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered missing code ND - Not Done; reason for	(b) (4)	04 Sep 2020 15:48:35
change Data Entry Error	(b) (4), (b) (6)	
User entered '130'	(b) (4), (b) (6)	07 Aug 2020 15:19:53

**US3002122**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User entered 'mmHg'	System	07 Aug 2020 15:19:53

**US3002122**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered missing code ND - Not Done; reason for	(b) (4)	04 Sep 2020 15:48:35
change Data Entry Error	(b) (4), (b) (6)	
User entered '85'	(b) (4), (b) (6)	07 Aug 2020 15:19:53

**US3002122**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User entered 'mmHg'	System	07 Aug 2020 15:19:53



**US3002122**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05

**US3002122**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05

**US3002122**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:50:29**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:20:21

US3002122

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 21:50:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	08 Sep 2020 04:54:26
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	04 Sep 2020 15:50:06
User entered '07 Aug 2020'	(b) (4), (b) (6)	07 Aug 2020 15:20:21

**US3002122**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:50:29**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '07 Aug 2020'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:20:31

**US3002122**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:50:29**

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:20:31

**US3002122**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:50:29**

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:20:31

**US3002122**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:50:29**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:20:31



**US3002122**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:50:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:20:31

**US3002122**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:50:29**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 15:20:31

**US3002122**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:50:29**

*If Post-menopausal, date of last menstruation (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:20:31

**US3002122**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:50:29**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:20:31

**US3002122**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:50:29**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:20:45

**US3002122**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:50:29**

**Date of test** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '07 Aug 2020'	(b) (4), (b) (6)	07 Aug 2020 15:20:45

**US3002122**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:50:29**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:20:45

**US3002122**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:50:29**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:20:45



US3002122

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User closed query 'Per CDM: As per the CCG Guidelines Page number 26, FSH sample collected: Yes OR No should be recorded, Kindly update accordingly.' (Site from DM).	(b) (4)	12 Oct 2020 06:11:54
Query 'Per CDM: As per the CCG Guidelines Page number 26, FSH sample collected: Yes OR No should be recorded, Kindly update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 17:56:20
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 17:56:11
User opened query 'Per CDM: As per the CCG Guidelines Page number 26, FSH sample collected: Yes OR No should be recorded, Kindly update accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 12:16:33
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 15:20:45

**US3002122**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:50:29**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 15:20:45

**US3002122**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:50:29**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 15:20:45

**US3002122**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:50:29**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User entered empty.	System	07 Aug 2020 15:20:45

US3002122

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:18:15

US3002122

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:18:15

US3002122

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

**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)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 15:18:15

US3002122

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

**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)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 15:18:15



US3002122

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:18:15

US3002122

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

[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)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 15:18:15

US3002122

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

**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)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 15:18:15

US3002122

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

**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)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 15:18:15

US3002122

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

[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)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:18:15

US3002122

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

**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)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 15:18:15

US3002122

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

**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)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 15:18:15

**US3002122**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 21:50:29**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 15:18:15



**US3002122**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 21:50:29**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Lab technician'	(b) (4), (b) (6)	07 Aug 2020 15:18:15

**US3002122**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 21:50:29**

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 15:18:15

**US3002122**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 21:50:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 15:18:15

US3002122

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

**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)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 15:18:15

US3002122

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

[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)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:18:15

US3002122

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:50:29

**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)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 15:18:15

**US3002122**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 21:50:29**

**Resides in a single family home** (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'I'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:18:15

**US3002122**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 21:50:29**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '0'	(b) (4), (b) (6)	07 Aug 2020 15:18:15



**US3002122**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 21:50:29**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 08:46:05
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 15:18:15

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:50:29**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:20:59

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:50:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '07 Aug 2020'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:20:59

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:50:29**

[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 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:20:59

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:50:29**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User entered 'VISIT1'	System	07 Aug 2020 15:20:59

US3002122

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '07 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 12:44:26

US3002122

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:50:29

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 02:45:52
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:45:52
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Aug 2020 12:44:26
User entered '101751' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 12:44:26

US3002122

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:50:29

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 12:44:26



**US3002122**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 21:50:29**

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 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 15:21:18

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 21:50:29**

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 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 15:21:18

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 21:50:29**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:21:18

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 21:50:29**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:21:18

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 21:50:29**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'No (N)'	(b) (4), (b) (6)	07 Aug 2020 15:21:18

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:50:29**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered missing code ND - Not Done; reason for	(b) (4)	04 Sep 2020 15:48:53
change Data Entry Error	(b) (4), (b) (6)	
User entered '167' cm	(b) (4), (b) (6)	07 Aug 2020 15:22:55

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:50:29**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered missing code ND - Not Done; reason for	(b) (4)	04 Sep 2020 15:48:53
change Data Entry Error	(b) (4), (b) (6)	
User entered '73.6' kg	(b) (4), (b) (6)	07 Aug 2020 15:22:55

US3002122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:50:29

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered missing code ND - Not Done; reason for	(b) (4)	04 Sep 2020 15:48:53
change Data Entry Error	(b) (4), (b) (6)	
User entered '167' cm	(b) (4), (b) (6)	07 Aug 2020 15:22:55



**US3002122**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:50:29**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 15:48:53
User entered '73.6' kg	(b) (4), (b) (6)	07 Aug 2020 15:22:55

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	07 Aug 2020 15:22:55

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:22:55

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:50:29**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '07 Aug 2020'	(b) (4), (b) (6)	07 Aug 2020 15:22:55

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:50:29**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '07:16'	(b) (4), (b) (6)	07 Aug 2020 15:22:55

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User entered '07 Aug 2020 07:16'	System	07 Aug 2020 15:22:55

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '36.7' C	(b) (4), (b) (6)	07 Aug 2020 15:22:55

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:22:55



**US3002122**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:50:29**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:22:55

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '66'	(b) (4), (b) (6)	07 Aug 2020 15:22:55

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User entered 'bpm'	System	07 Aug 2020 15:22:55

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '16'	(b) (4), (b) (6)	07 Aug 2020 15:22:55

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User entered 'breaths/min'	System	07 Aug 2020 15:22:55

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '130'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:22:55

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User entered 'mmHg'	System	07 Aug 2020 15:22:55

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '85'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:22:55



**US3002122**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User entered 'mmHg'	System	07 Aug 2020 15:22:55

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:50:29**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered missing code ND - Not Done; reason for	(b) (4)	04 Sep 2020 15:48:53
change Data Entry Error	(b) (4), (b) (6)	
User entered '167' cm	(b) (4), (b) (6)	07 Aug 2020 15:22:55

US3002122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:50:29

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered missing code ND - Not Done; reason for	(b) (4)	
change Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 15:48:53
User entered '73.6' kg	(b) (4), (b) (6)	07 Aug 2020 15:22:55

US3002122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	07 Aug 2020 15:22:55

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:22:55

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:50:29**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '07 Aug 2020'	(b) (4), (b) (6)	07 Aug 2020 15:22:55

US3002122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4)	11 Aug 2020 08:49:25
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Data correct as entered.	(b) (4), (b) (6)	07 Aug 2020 15:23:02
' (Site from System).		
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		07 Aug 2020 15:22:55
User entered '08:35'	(b) (4), (b) (6)	07 Aug 2020 15:22:55

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User entered '07 Aug 2020 08:35'	System	07 Aug 2020 15:22:55



**US3002122**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '36.9' C	(b) (4), (b) (6)	07 Aug 2020 15:22:55

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:22:55

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:50:29**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 15:22:55

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '57'	(b) (4), (b) (6)	07 Aug 2020 15:22:55

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User entered 'bpm'	System	07 Aug 2020 15:22:55

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '16'	(b) (4), (b) (6)	07 Aug 2020 15:22:55

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User entered 'breaths/min'	System	07 Aug 2020 15:22:55

US3002122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '135'	(b) (4), (b) (6)	07 Aug 2020 15:22:55



**US3002122**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User entered 'mmHg'	System	07 Aug 2020 15:22:55

US3002122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '82'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:22:55

US3002122

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:50:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User entered 'mmHg'	System	07 Aug 2020 15:22:55

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:50:29**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:23:10

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:50:29**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '07 Aug 2020'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:23:10

US3002122

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User closed query 'Per CDM: Please consider entering "No" for this field and remove Date of test, Test performed and Result as screening and VID1 have occurred on the same day.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 06:12:00
' (Site from DM). Query 'Per CDM: Please consider entering "No" for this field and remove Date of test, Test performed and Result as screening and VID1 have occurred on the same day.	(b) (4), (b) (6)	09 Oct 2020 17:56:50
' answered with 'updated' (Site from DM). User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 17:56:45
User opened query 'Per CDM: Please consider entering "No" for this field and remove Date of test, Test performed and Result as screening and VID1 have occurred on the same day.	(b) (4), (b) (6)	08 Oct 2020 12:15:53
' (Site from DM). User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Aug 2020 15:23:21

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:50:29**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty; reason for change Data Entry Error	(b) (4)	09 Oct 2020 17:56:45
User entered '07 Aug 2020'	(b) (4), (b) (6)	07 Aug 2020 15:23:21

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:50:29**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty; reason for change Data Entry Error	(b) (4)	09 Oct 2020 17:56:45
User entered 'Urine (URINE)'	(b) (4), (b) (6)	07 Aug 2020 15:23:21



**US3002122**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:50:29**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty; reason for change Data Entry Error	(b) (4)	09 Oct 2020 17:56:45
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	07 Aug 2020 15:23:21

US3002122

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User closed query 'Per CDM: As per the CCG Guidelines Page number 26, FSH sample collected: Yes OR No should be recorded, Kindly update accordingly.' (Site from DM).	(b) (4)	12 Oct 2020 06:12:03
Query 'Per CDM: As per the CCG Guidelines Page number 26, FSH sample collected: Yes OR No should be recorded, Kindly update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 17:56:54
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Oct 2020 17:56:45
User opened query 'Per CDM: As per the CCG Guidelines Page number 26, FSH sample collected: Yes OR No should be recorded, Kindly update accordingly.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 12:16:17
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 15:23:21

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:50:29**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:23:21

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:50:29**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4)	07 Aug 2020 15:23:21

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:50:29**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User entered empty.	System	07 Aug 2020 15:23:21

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:50:29**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Yes (Y)'	Jessica Satorie (b) (4)	07 Aug 2020 13:10:06

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:50:29**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	Jessica Satorie (b) (4)	07 Aug 2020 13:10:06

US3002122

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

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 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	Jessica Satorie (b) (4)	07 Aug 2020 13:10:06



**US3002122**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:50:29**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User entered 'MRNA-1273 OR PLACEBO'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:50:29**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '07 Aug 2020'	Jessica Satorie (b) (4)	07 Aug 2020 13:10:06

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:50:29**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '08:04'	Jessica Satorie (b) (4)	07 Aug 2020 13:10:06

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:50:29**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User entered '07 Aug 2020 08:04'	System	07 Aug 2020 13:10:06

US3002122

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Left Arm (LEFT ARM)'	Jessica Satorie (b) (4)	07 Aug 2020 13:10:06

US3002122

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User entered 'ONCE'	System	07 Aug 2020 13:10:06

US3002122

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User entered 'INTRAMUSCULAR'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:50:29**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:23:57



**US3002122**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:50:29**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '07 Aug 2020'	(b) (4), (b) (6)	07 Aug 2020 15:23:57

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:50:29**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '07:35'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:23:57

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:50:29**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User entered '07 Aug 2020 07:35'	System	07 Aug 2020 15:23:57

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 11 Aug 2021 21:50:29**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '07 Aug 2020'	(b) (4), (b) (6)	07 Aug 2020 15:24:20

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	07 Aug 2020 15:24:20

US3002122

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:50:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:24:20

US3002122

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:50:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	(b) (4)	10 Aug 2020 15:55:24
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	10 Aug 2020 15:55:24
User entered '07:36' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Aug 2020 15:55:24
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	07 Aug 2020 15:24:20
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 15:24:20

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User entered '07 Aug 2020 07:36'	System	10 Aug 2020 15:55:24
User entered empty.	System	07 Aug 2020 15:24:20



**US3002122**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	07 Aug 2020 15:24:20

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:24:20

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:50:29**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 15:24:20

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User entered empty.	System	07 Aug 2020 15:24:20

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:50:29**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:24:29

**US3002122**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:50:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User entered 'I'	System	07 Aug 2020 15:24:29

US3002122

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 21:50:29**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-07T08:34:41', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '68d7f623-0c42-4079-8c56-64fb6755595c'	System	07 Aug 2020 13:35:11
User entered 'Yes (Y)'	System	07 Aug 2020 13:35:11



US3002122

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-07T08:34:58', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '68d7f623-0c42-4079-8c56-64fb6755595c'	System	07 Aug 2020 13:35:11
User entered '98.5'	System	07 Aug 2020 13:35:11

US3002122

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-07T08:35:02', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '68d7f623-0c42-4079-8c56-64fb6755595c'	System	07 Aug 2020 13:35:11
User entered 'No (N)'	System	07 Aug 2020 13:35:11

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-07T08:35:11', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '68d7f623-0c42-4079-8c56-64fb6755595c'	System	07 Aug 2020 13:35:11
User entered '07 Aug 2020 08:35'	System	07 Aug 2020 13:35:11

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '07 Aug 2020 08:24'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '07 Aug 2020 10:54'	System	07 Aug 2020 13:10:06

US3002122

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 13:10:06

US3002122

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-07T11:53:37', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '7e51c7fe-6812-4345-9f7c-b0c9a53dfbcc'	System	07 Aug 2020 16:53:50
User entered 'Yes (Y)'	System	07 Aug 2020 16:53:50

US3002122

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-07T11:53:41', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '7e51c7fe-6812-4345-9f7c-b0c9a53dfbcc'	System	07 Aug 2020 16:53:50
User entered '98.2'	System	07 Aug 2020 16:53:50



US3002122

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-07T11:53:44', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '7e51c7fe-6812-4345-9f7c-b0c9a53dfbcc'	System	07 Aug 2020 16:53:50
User entered 'No (N)'	System	07 Aug 2020 16:53:50

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-07T11:53:47', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '7e51c7fe-6812-4345-9f7c-b0c9a53dfbcc'	System	07 Aug 2020 16:53:50
User entered '07 Aug 2020 11:53'	System	07 Aug 2020 16:53:50

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '07 Aug 2020 11:49'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered 'Day 2'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 21:50:29**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-08T12:15:56', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'f8778b21-4e37-4045-a980-bae92998de9f'	System	08 Aug 2020 17:16:11
User entered 'Yes (Y)'	System	08 Aug 2020 17:16:11

US3002122

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:50:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-08T12:16:01', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'f8778b21-4e37-4045-a980-bae92998de9f'	System	08 Aug 2020 17:16:11
User entered '98.0'	System	08 Aug 2020 17:16:11

US3002122

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-08T12:16:05', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'f8778b21-4e37-4045-a980-bae92998de9f'	System	08 Aug 2020 17:16:11
User entered 'No (N)'	System	08 Aug 2020 17:16:11



**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-08T12:16:11', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'f8778b21-4e37-4045-a980-bae92998de9f'	System	08 Aug 2020 17:16:11
User entered '08 Aug 2020 12:16'	System	08 Aug 2020 17:16:11

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 13:10:06

US3002122

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered 'Day 3'	System	07 Aug 2020 13:10:06

US3002122

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:50:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-09T12:02:30', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '12886df7-b84a-441c-acac-4470e16be0f5'	System	09 Aug 2020 17:02:44
User entered 'Yes (Y)'	System	09 Aug 2020 17:02:44

US3002122

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:50:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-09T12:02:36', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '12886df7-b84a-441c-acac-4470e16be0f5'	System	09 Aug 2020 17:02:44
User entered '97.8'	System	09 Aug 2020 17:02:44

US3002122

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-09T12:02:39', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '12886df7-b84a-441c-acac-4470e16be0f5'	System	09 Aug 2020 17:02:44
User entered 'No (N)'	System	09 Aug 2020 17:02:44

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-09T12:02:41', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '12886df7-b84a-441c-acac-4470e16be0f5'	System	09 Aug 2020 17:02:44
User entered '09 Aug 2020 12:02'	System	09 Aug 2020 17:02:44



**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 13:10:06

US3002122

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered 'Day 4'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 21:50:29**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-10T13:45:34', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '929d33e7-e4ef-4c16-8277-270a3e309d25'	System	10 Aug 2020 18:45:45
User entered 'Yes (Y)'	System	10 Aug 2020 18:45:45

US3002122

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:50:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-10T13:45:39', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '929d33e7-e4ef-4c16-8277-270a3e309d25'	System	10 Aug 2020 18:45:45
User entered '98.1'	System	10 Aug 2020 18:45:45

US3002122

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-10T13:45:42', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '929d33e7-e4ef-4c16-8277-270a3e309d25'	System	10 Aug 2020 18:45:45
User entered 'No (N)'	System	10 Aug 2020 18:45:45

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-10T13:45:45', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '929d33e7-e4ef-4c16-8277-270a3e309d25'	System	10 Aug 2020 18:45:45
User entered '10 Aug 2020 13:45'	System	10 Aug 2020 18:45:45

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 13:10:06



**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered 'Day 5'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 21:50:29**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-11T12:01:31', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '55760e4d-8eba-42e5-8a0d-01bbd0e79a18'	System	11 Aug 2020 17:01:41
User entered 'Yes (Y)'	System	11 Aug 2020 17:01:41

US3002122

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:50:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-11T12:01:35', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '55760e4d-8eba-42e5-8a0d-01bbd0e79a18'	System	11 Aug 2020 17:01:41
User entered '98.2'	System	11 Aug 2020 17:01:41

US3002122

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-11T12:01:38', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '55760e4d-8eba-42e5-8a0d-01bbd0e79a18'	System	11 Aug 2020 17:01:41
User entered 'No (N)'	System	11 Aug 2020 17:01:41

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-11T12:01:40', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '55760e4d-8eba-42e5-8a0d-01bbd0e79a18'	System	11 Aug 2020 17:01:41
User entered '11 Aug 2020 12:01'	System	11 Aug 2020 17:01:41

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 13:10:06



US3002122

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered 'Day 6'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 21:50:29**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-12T13:58:25', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '90dde6c7-6e7c-4ef8-83c3-e2a74bb145f8'	System	12 Aug 2020 18:58:40
User entered 'Yes (Y)'	System	12 Aug 2020 18:58:40

US3002122

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:50:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-12T13:58:33', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '90dde6c7-6e7c-4ef8-83c3-e2a74bb145f8'	System	12 Aug 2020 18:58:40
User entered '96.1'	System	12 Aug 2020 18:58:40

US3002122

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-12T13:58:36', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '90dde6c7-6e7c-4ef8-83c3-e2a74bb145f8'	System	12 Aug 2020 18:58:40
User entered 'No (N)'	System	12 Aug 2020 18:58:40

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-12T13:58:39', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '90dde6c7-6e7c-4ef8-83c3-e2a74bb145f8'	System	12 Aug 2020 18:58:40
User entered '12 Aug 2020 13:58'	System	12 Aug 2020 18:58:40

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 13:10:06

US3002122

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered 'Day 7'	System	07 Aug 2020 13:10:06



US3002122

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:50:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-13T13:58:17', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '19a8dded-e6df-4729-9b79-56cffc1025cc'	System	13 Aug 2020 18:58:25
User entered 'Yes (Y)'	System	13 Aug 2020 18:58:25

US3002122

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:50:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-13T13:58:20', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '19a8dded-e6df-4729-9b79-56cffc1025cc'	System	13 Aug 2020 18:58:25
User entered '98.0'	System	13 Aug 2020 18:58:25

US3002122

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-13T13:58:24', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '19a8dded-e6df-4729-9b79-56cffc1025cc'	System	13 Aug 2020 18:58:25
User entered 'No (N)'	System	13 Aug 2020 18:58:25

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-13T13:58:26', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '19a8dded-e6df-4729-9b79-56cffc1025cc'	System	13 Aug 2020 18:58:25
User entered '13 Aug 2020 13:58'	System	13 Aug 2020 18:58:25

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 13:10:06

US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-07T08:35:37', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '1bbe08f4-41a3-400c-b301-131a53e9b18c'	System	07 Aug 2020 13:35:52
User entered 'None (1)'	System	07 Aug 2020 13:35:52



US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-07T08:35:39', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '1bbe08f4-41a3-400c-b301-131a53e9b18c'	System	07 Aug 2020 13:35:52
User entered 'No (N)'	System	07 Aug 2020 13:35:52

US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-07T08:35:42', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '1bbe08f4-41a3-400c-b301-131a53e9b18c'	System	07 Aug 2020 13:35:52
User entered 'No (N)'	System	07 Aug 2020 13:35:52

US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-07T08:35:48', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '1bbe08f4-41a3-400c-b301-131a53e9b18c'	System	07 Aug 2020 13:35:52
User entered 'None (1)'	System	07 Aug 2020 13:35:52

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-07T08:35:51', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '1bbe08f4-41a3-400c-b301-131a53e9b18c'	System	07 Aug 2020 13:35:52
User entered '07 Aug 2020 08:35'	System	07 Aug 2020 13:35:52

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '07 Aug 2020 08:24'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '07 Aug 2020 10:54'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 13:10:06

US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-07T11:50:13', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'f4e4b917-41e7-4240-b167-32b17e6e9fe2'	System	07 Aug 2020 16:50:27
User entered 'None (1)'	System	07 Aug 2020 16:50:27



US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-07T11:50:16', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'f4e4b917-41e7-4240-b167-32b17e6e9fe2'	System	07 Aug 2020 16:50:27
User entered 'No (N)'	System	07 Aug 2020 16:50:27

US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-07T11:50:19', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'f4e4b917-41e7-4240-b167-32b17e6e9fe2'	System	07 Aug 2020 16:50:27
User entered 'No (N)'	System	07 Aug 2020 16:50:27

US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-07T11:50:23', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'f4e4b917-41e7-4240-b167-32b17e6e9fe2'	System	07 Aug 2020 16:50:27
User entered 'None (1)'	System	07 Aug 2020 16:50:27

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-07T11:50:26', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'f4e4b917-41e7-4240-b167-32b17e6e9fe2'	System	07 Aug 2020 16:50:27
User entered '07 Aug 2020 11:50'	System	07 Aug 2020 16:50:27

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '07 Aug 2020 11:49'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered 'Day 2'	System	07 Aug 2020 13:10:06

US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-08T12:16:17', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '0785d06d-377c-4e17-8686-f96073796517'	System	08 Aug 2020 17:16:28
User entered 'None (1)'	System	08 Aug 2020 17:16:28



US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:50:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-08T12:16:19', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '0785d06d-377c-4e17-8686-f96073796517'	System	08 Aug 2020 17:16:28
User entered 'No (N)'	System	08 Aug 2020 17:16:28

US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-08T12:16:21', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '0785d06d-377c-4e17-8686-f96073796517'	System	08 Aug 2020 17:16:28
User entered 'No (N)'	System	08 Aug 2020 17:16:28

US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-08T12:16:24', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '0785d06d-377c-4e17-8686-f96073796517'	System	08 Aug 2020 17:16:28
User entered 'None (1)'	System	08 Aug 2020 17:16:28

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-08T12:16:27', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '0785d06d-377c-4e17-8686-f96073796517'	System	08 Aug 2020 17:16:28
User entered '08 Aug 2020 12:16'	System	08 Aug 2020 17:16:28

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 13:10:06

US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered 'Day 3'	System	07 Aug 2020 13:10:06

US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-09T12:01:04', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '898d0d25-d050-46df-a316-e9ab1b960d3b'	System	09 Aug 2020 17:01:16
User entered 'None (1)'	System	09 Aug 2020 17:01:16



US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:50:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-09T12:01:06', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '898d0d25-d050-46df-a316-e9ab1b960d3b'	System	09 Aug 2020 17:01:16
User entered 'No (N)'	System	09 Aug 2020 17:01:16

US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-09T12:01:09', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '898d0d25-d050-46df-a316-e9ab1b960d3b'	System	09 Aug 2020 17:01:16
User entered 'No (N)'	System	09 Aug 2020 17:01:16

US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-09T12:01:12', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '898d0d25-d050-46df-a316-e9ab1b960d3b'	System	09 Aug 2020 17:01:16
User entered 'None (1)'	System	09 Aug 2020 17:01:16

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-09T12:01:14', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '898d0d25-d050-46df-a316-e9ab1b960d3b'	System	09 Aug 2020 17:01:16
User entered '09 Aug 2020 12:01'	System	09 Aug 2020 17:01:16

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 13:10:06

US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered 'Day 4'	System	07 Aug 2020 13:10:06

US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-10T13:45:02', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'f58a4c8c-12c1-4a28-a599-4dc8813a9dc7'	System	10 Aug 2020 18:45:32
User entered 'None (1)'	System	10 Aug 2020 18:45:32



US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:50:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-10T13:45:05', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'f58a4c8c-12c1-4a28-a599-4dc8813a9dc7'	System	10 Aug 2020 18:45:32
User entered 'No (N)'	System	10 Aug 2020 18:45:32

US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-10T13:45:12', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'f58a4c8c-12c1-4a28-a599-4dc8813a9dc7'	System	10 Aug 2020 18:45:32
User entered 'No (N)'	System	10 Aug 2020 18:45:32

US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-10T13:45:26', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'f58a4c8c-12c1-4a28-a599-4dc8813a9dc7'	System	10 Aug 2020 18:45:32
User entered 'None (1)'	System	10 Aug 2020 18:45:32

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-10T13:45:28', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'f58a4c8c-12c1-4a28-a599-4dc8813a9dc7'	System	10 Aug 2020 18:45:32
User entered '10 Aug 2020 13:45'	System	10 Aug 2020 18:45:32

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered 'Day 5'	System	07 Aug 2020 13:10:06

US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-11T12:01:15', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'd73294e7-5c75-4743-916b-a028a9080e6c'	System	11 Aug 2020 17:01:28
User entered 'None (1)'	System	11 Aug 2020 17:01:28



US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:50:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-11T12:01:19', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'd73294e7-5c75-4743-916b-a028a9080e6c'	System	11 Aug 2020 17:01:28
User entered 'No (N)'	System	11 Aug 2020 17:01:28

US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-11T12:01:20', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'd73294e7-5c75-4743-916b-a028a9080e6c'	System	11 Aug 2020 17:01:28
User entered 'No (N)'	System	11 Aug 2020 17:01:28

US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-11T12:01:23', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'd73294e7-5c75-4743-916b-a028a9080e6c'	System	11 Aug 2020 17:01:28
User entered 'None (1)'	System	11 Aug 2020 17:01:28

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-11T12:01:25', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'd73294e7-5c75-4743-916b-a028a9080e6c'	System	11 Aug 2020 17:01:28
User entered '11 Aug 2020 12:01'	System	11 Aug 2020 17:01:28

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 13:10:06

US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered 'Day 6'	System	07 Aug 2020 13:10:06

US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-12T13:57:24', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'ca9371c0-98f6-435f-81de-ca6976c1ab4f'	System	12 Aug 2020 18:57:35
User entered 'None (1)'	System	12 Aug 2020 18:57:35



US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:50:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-12T13:57:27', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'ca9371c0-98f6-435f-81de-ca6976c1ab4f'	System	12 Aug 2020 18:57:35
User entered 'No (N)'	System	12 Aug 2020 18:57:35

US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-12T13:57:29', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'ca9371c0-98f6-435f-81de-ca6976c1ab4f'	System	12 Aug 2020 18:57:35
User entered 'No (N)'	System	12 Aug 2020 18:57:35

US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-12T13:57:32', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'ca9371c0-98f6-435f-81de-ca6976c1ab4f'	System	12 Aug 2020 18:57:35
User entered 'None (1)'	System	12 Aug 2020 18:57:35

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-12T13:57:35', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'ca9371c0-98f6-435f-81de-ca6976c1ab4f'	System	12 Aug 2020 18:57:35
User entered '12 Aug 2020 13:57'	System	12 Aug 2020 18:57:35

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered 'Day 7'	System	07 Aug 2020 13:10:06

US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-13T13:58:29', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'c8fc364a-3e5c-418f-bad0-a59966bcbe77'	System	13 Aug 2020 18:58:39
User entered 'None (1)'	System	13 Aug 2020 18:58:39



US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:50:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-13T13:58:31', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'c8fc364a-3e5c-418f-bad0-a59966bcbe77'	System	13 Aug 2020 18:58:39
User entered 'No (N)'	System	13 Aug 2020 18:58:39

US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-13T13:58:32', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'c8fc364a-3e5c-418f-bad0-a59966bcbe77'	System	13 Aug 2020 18:58:39
User entered 'No (N)'	System	13 Aug 2020 18:58:39

US3002122

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-13T13:58:34', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'c8fc364a-3e5c-418f-bad0-a59966bcbe77'	System	13 Aug 2020 18:58:39
User entered 'None (1)'	System	13 Aug 2020 18:58:39

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-13T13:58:36', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'c8fc364a-3e5c-418f-bad0-a59966bcbe77'	System	13 Aug 2020 18:58:39
User entered '13 Aug 2020 13:58'	System	13 Aug 2020 18:58:39

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:50:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-07T08:36:08', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '25f94f8b-0b42-4447-8141-cc60a0e50793'	System	07 Aug 2020 13:36:27
User entered 'None (0)'	System	07 Aug 2020 13:36:27



**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:50:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-07T08:36:11', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '25f94f8b-0b42-4447-8141-cc60a0e50793'	System	07 Aug 2020 13:36:27
User entered 'None (0)'	System	07 Aug 2020 13:36:27

US3002122

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-07T08:36:15', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '25f94f8b-0b42-4447-8141-cc60a0e50793'	System	07 Aug 2020 13:36:27
User entered 'None (0)'	System	07 Aug 2020 13:36:27

US3002122

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-07T08:36:17', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '25f94f8b-0b42-4447-8141-cc60a0e50793'	System	07 Aug 2020 13:36:27
User entered 'None (0)'	System	07 Aug 2020 13:36:27

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:50:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-07T08:36:19', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '25f94f8b-0b42-4447-8141-cc60a0e50793'	System	07 Aug 2020 13:36:27
User entered 'None (0)'	System	07 Aug 2020 13:36:27

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:50:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-07T08:36:21', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '25f94f8b-0b42-4447-8141-cc60a0e50793'	System	07 Aug 2020 13:36:27
User entered 'None (0)'	System	07 Aug 2020 13:36:27

US3002122

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

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)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-07T08:36:25', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '25f94f8b-0b42-4447-8141-cc60a0e50793'	System	07 Aug 2020 13:36:27
User entered 'No (N)'	System	07 Aug 2020 13:36:27

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-07T08:36:27', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '25f94f8b-0b42-4447-8141-cc60a0e50793'	System	07 Aug 2020 13:36:27
User entered '07 Aug 2020 08:36'	System	07 Aug 2020 13:36:27

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '07 Aug 2020 08:24'	System	07 Aug 2020 13:10:06



**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '07 Aug 2020 10:54'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:50:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-07T11:50:34', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '07c0d4fd-81cd-4aed-b377-5f2b290f83fd'	System	07 Aug 2020 16:50:55
User entered 'None (0)'	System	07 Aug 2020 16:50:55

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:50:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-07T11:50:38', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '07c0d4fd-81cd-4aed-b377-5f2b290f83fd'	System	07 Aug 2020 16:50:55
User entered 'None (0)'	System	07 Aug 2020 16:50:55

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:50:29**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-07T11:50:40', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '07c0d4fd-81cd-4aed-b377-5f2b290f83fd'	System	07 Aug 2020 16:50:55
User entered 'None (0)'	System	07 Aug 2020 16:50:55

US3002122

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-07T11:50:43', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '07c0d4fd-81cd-4aed-b377-5f2b290f83fd'	System	07 Aug 2020 16:50:55
User entered 'None (0)'	System	07 Aug 2020 16:50:55

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:50:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-07T11:50:46', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '07c0d4fd-81cd-4aed-b377-5f2b290f83fd'	System	07 Aug 2020 16:50:55
User entered 'None (0)'	System	07 Aug 2020 16:50:55

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:50:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-07T11:50:48', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '07c0d4fd-81cd-4aed-b377-5f2b290f83fd'	System	07 Aug 2020 16:50:55
User entered 'None (0)'	System	07 Aug 2020 16:50:55



US3002122

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

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)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-07T11:50:52', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '07c0d4fd-81cd-4aed-b377-5f2b290f83fd'	System	07 Aug 2020 16:50:55
User entered 'No (N)'	System	07 Aug 2020 16:50:55

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-07T11:50:55', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '07c0d4fd-81cd-4aed-b377-5f2b290f83fd'	System	07 Aug 2020 16:50:55
User entered '07 Aug 2020 11:50'	System	07 Aug 2020 16:50:55

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '07 Aug 2020 11:49'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered 'Day 2'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:50:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-08T12:16:32', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'dddd3fa9-70af-4cfb-9252-12efb1186eff'	System	08 Aug 2020 17:16:50
User entered 'None (0)'	System	08 Aug 2020 17:16:50

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:50:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-08T12:16:35', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'dddd3fa9-70af-4cfb-9252-12efb1186eff'	System	08 Aug 2020 17:16:50
User entered 'None (0)'	System	08 Aug 2020 17:16:50

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:50:29**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-08T12:16:38', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'dddd3fa9-70af-4cfb-9252-12efb1186eff'	System	08 Aug 2020 17:16:50
User entered 'None (0)'	System	08 Aug 2020 17:16:50



**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:50:29**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-08T12:16:39', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'dddd3fa9-70af-4cfb-9252-12efb1186eff'	System	08 Aug 2020 17:16:50
User entered 'None (0)'	System	08 Aug 2020 17:16:50

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:50:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-08T12:16:41', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'dddd3fa9-70af-4cfb-9252-12efb1186eff'	System	08 Aug 2020 17:16:50
User entered 'None (0)'	System	08 Aug 2020 17:16:50

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:50:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-08T12:16:43', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'dddd3fa9-70af-4cfb-9252-12efb1186eff'	System	08 Aug 2020 17:16:50
User entered 'None (0)'	System	08 Aug 2020 17:16:50

US3002122

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:50:29

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)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-08T12:16:47', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'dddd3fa9-70af-4cfb-9252-12efb1186eff'	System	08 Aug 2020 17:16:50
User entered 'No (N)'	System	08 Aug 2020 17:16:50

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-08T12:16:48', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'dddd3fa9-70af-4cfb-9252-12efb1186eff'	System	08 Aug 2020 17:16:50
User entered '08 Aug 2020 12:16'	System	08 Aug 2020 17:16:50

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered 'Day 3'	System	07 Aug 2020 13:10:06



**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:50:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-09T12:01:18', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '6c5e7c13-8a5b-4f78-bb38-d16c6e2f3b23'	System	09 Aug 2020 17:01:36
User entered 'None (0)'	System	09 Aug 2020 17:01:36

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:50:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-09T12:01:20', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '6c5e7c13-8a5b-4f78-bb38-d16c6e2f3b23'	System	09 Aug 2020 17:01:36
User entered 'None (0)'	System	09 Aug 2020 17:01:36

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:50:29**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-09T12:01:22', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '6c5e7c13-8a5b-4f78-bb38-d16c6e2f3b23'	System	09 Aug 2020 17:01:36
User entered 'None (0)'	System	09 Aug 2020 17:01:36

US3002122

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:50:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-09T12:01:24', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '6c5e7c13-8a5b-4f78-bb38-d16c6e2f3b23'	System	09 Aug 2020 17:01:36
User entered 'None (0)'	System	09 Aug 2020 17:01:36

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:50:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-09T12:01:26', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '6c5e7c13-8a5b-4f78-bb38-d16c6e2f3b23'	System	09 Aug 2020 17:01:36
User entered 'None (0)'	System	09 Aug 2020 17:01:36

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:50:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-09T12:01:28', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '6c5e7c13-8a5b-4f78-bb38-d16c6e2f3b23'	System	09 Aug 2020 17:01:36
User entered 'None (0)'	System	09 Aug 2020 17:01:36

US3002122

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:50:29

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)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-09T12:01:30', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '6c5e7c13-8a5b-4f78-bb38-d16c6e2f3b23'	System	09 Aug 2020 17:01:36
User entered 'No (N)'	System	09 Aug 2020 17:01:36

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-09T12:01:33', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '6c5e7c13-8a5b-4f78-bb38-d16c6e2f3b23'	System	09 Aug 2020 17:01:36
User entered '09 Aug 2020 12:01'	System	09 Aug 2020 17:01:36



**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 13:10:06

US3002122

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered 'Day 4'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:50:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-10T13:44:45', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '834d05ab-9015-4b49-8e74-a2063895c6a3'	System	10 Aug 2020 18:44:58
User entered 'None (0)'	System	10 Aug 2020 18:44:58

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:50:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-10T13:44:46', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '834d05ab-9015-4b49-8e74-a2063895c6a3'	System	10 Aug 2020 18:44:58
User entered 'None (0)'	System	10 Aug 2020 18:44:58

US3002122

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:50:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-10T13:44:48', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '834d05ab-9015-4b49-8e74-a2063895c6a3'	System	10 Aug 2020 18:44:58
User entered 'None (0)'	System	10 Aug 2020 18:44:58

US3002122

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:50:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-10T13:44:50', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '834d05ab-9015-4b49-8e74-a2063895c6a3'	System	10 Aug 2020 18:44:58
User entered 'None (0)'	System	10 Aug 2020 18:44:58

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:50:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-10T13:44:52', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '834d05ab-9015-4b49-8e74-a2063895c6a3'	System	10 Aug 2020 18:44:58
User entered 'None (0)'	System	10 Aug 2020 18:44:58



**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:50:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-10T13:44:53', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '834d05ab-9015-4b49-8e74-a2063895c6a3'	System	10 Aug 2020 18:44:58
User entered 'None (0)'	System	10 Aug 2020 18:44:58

US3002122

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:50:29

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)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-10T13:44:56', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '834d05ab-9015-4b49-8e74-a2063895c6a3'	System	10 Aug 2020 18:44:58
User entered 'No (N)'	System	10 Aug 2020 18:44:58

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-10T13:44:58', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '834d05ab-9015-4b49-8e74-a2063895c6a3'	System	10 Aug 2020 18:44:58
User entered '10 Aug 2020 13:44'	System	10 Aug 2020 18:44:58

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered 'Day 5'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:50:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-11T12:01:45', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '22aecc32-bc4d-4f59-9840-cf425aca9175'	System	11 Aug 2020 17:02:07
User entered 'None (0)'	System	11 Aug 2020 17:02:07

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:50:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-11T12:01:47', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '22aecc32-bc4d-4f59-9840-cf425aca9175'	System	11 Aug 2020 17:02:07
User entered 'None (0)'	System	11 Aug 2020 17:02:07



**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:50:29**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-11T12:01:49', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '22aecc32-bc4d-4f59-9840-cf425aca9175'	System	11 Aug 2020 17:02:07
User entered 'None (0)'	System	11 Aug 2020 17:02:07

US3002122

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:50:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-11T12:01:51', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '22aecc32-bc4d-4f59-9840-cf425aca9175'	System	11 Aug 2020 17:02:07
User entered 'None (0)'	System	11 Aug 2020 17:02:07

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:50:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-11T12:01:53', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '22aecc32-bc4d-4f59-9840-cf425aca9175'	System	11 Aug 2020 17:02:07
User entered 'None (0)'	System	11 Aug 2020 17:02:07

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:50:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-11T12:01:54', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '22aecc32-bc4d-4f59-9840-cf425aca9175'	System	11 Aug 2020 17:02:07
User entered 'None (0)'	System	11 Aug 2020 17:02:07

US3002122

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:50:29

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)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-11T12:02:03', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '22aecc32-bc4d-4f59-9840-cf425aca9175'	System	11 Aug 2020 17:02:07
User entered 'No (N)'	System	11 Aug 2020 17:02:07

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-11T12:02:05', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '22aecc32-bc4d-4f59-9840-cf425aca9175'	System	11 Aug 2020 17:02:07
User entered '11 Aug 2020 12:02'	System	11 Aug 2020 17:02:07

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 13:10:06



**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered 'Day 6'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:50:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-12T13:57:39', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '0acd5144-7abb-4ef7-a17b-53da6816068a'	System	12 Aug 2020 18:57:55
User entered 'None (0)'	System	12 Aug 2020 18:57:55

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:50:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-12T13:57:41', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '0acd5144-7abb-4ef7-a17b-53da6816068a'	System	12 Aug 2020 18:57:55
User entered 'None (0)'	System	12 Aug 2020 18:57:55

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:50:29**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-12T13:57:43', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '0acd5144-7abb-4ef7-a17b-53da6816068a'	System	12 Aug 2020 18:57:55
User entered 'None (0)'	System	12 Aug 2020 18:57:55

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:50:29**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-12T13:57:44', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '0acd5144-7abb-4ef7-a17b-53da6816068a'	System	12 Aug 2020 18:57:55
User entered 'None (0)'	System	12 Aug 2020 18:57:55

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:50:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-12T13:57:46', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '0acd5144-7abb-4ef7-a17b-53da6816068a'	System	12 Aug 2020 18:57:55
User entered 'None (0)'	System	12 Aug 2020 18:57:55

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:50:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-12T13:57:48', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '0acd5144-7abb-4ef7-a17b-53da6816068a'	System	12 Aug 2020 18:57:55
User entered 'None (0)'	System	12 Aug 2020 18:57:55

US3002122

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:50:29

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)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-12T13:57:51', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '0acd5144-7abb-4ef7-a17b-53da6816068a'	System	12 Aug 2020 18:57:55
User entered 'No (N)'	System	12 Aug 2020 18:57:55



**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-12T13:57:53', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '0acd5144-7abb-4ef7-a17b-53da6816068a'	System	12 Aug 2020 18:57:55
User entered '12 Aug 2020 13:57'	System	12 Aug 2020 18:57:55

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered 'Day 7'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:50:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-13T13:58:39', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '188a610e-3595-47b9-bc30-0254d2fd5542'	System	13 Aug 2020 18:58:50
User entered 'None (0)'	System	13 Aug 2020 18:58:50

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:50:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-13T13:58:40', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '188a610e-3595-47b9-bc30-0254d2fd5542'	System	13 Aug 2020 18:58:50
User entered 'None (0)'	System	13 Aug 2020 18:58:50

US3002122

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:50:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-13T13:58:42', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '188a610e-3595-47b9-bc30-0254d2fd5542'	System	13 Aug 2020 18:58:50
User entered 'None (0)'	System	13 Aug 2020 18:58:50

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:50:29**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-13T13:58:43', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '188a610e-3595-47b9-bc30-0254d2fd5542'	System	13 Aug 2020 18:58:50
User entered 'None (0)'	System	13 Aug 2020 18:58:50



**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:50:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-13T13:58:45', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '188a610e-3595-47b9-bc30-0254d2fd5542'	System	13 Aug 2020 18:58:50
User entered 'None (0)'	System	13 Aug 2020 18:58:50

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:50:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-13T13:58:46', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '188a610e-3595-47b9-bc30-0254d2fd5542'	System	13 Aug 2020 18:58:50
User entered 'None (0)'	System	13 Aug 2020 18:58:50

US3002122

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:50:29

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)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-13T13:58:48', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '188a610e-3595-47b9-bc30-0254d2fd5542'	System	13 Aug 2020 18:58:50
User entered 'No (N)'	System	13 Aug 2020 18:58:50

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-08-13T13:58:50', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '188a610e-3595-47b9-bc30-0254d2fd5542'	System	13 Aug 2020 18:58:50
User entered '13 Aug 2020 13:58'	System	13 Aug 2020 18:58:50

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 13:10:06

**US3002122**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:50:29**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:30:12

**US3002122**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:50:29**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '14 Aug 2020'	(b) (4), (b) (6)	17 Aug 2020 14:30:12



**US3002122**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:50:29**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	17 Aug 2020 14:30:12

**US3002122**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:50:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 14:30:12

**US3002122**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:50:29**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:30:18

**US3002122**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:50:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User entered 'I'	System	17 Aug 2020 14:30:18

**US3002122**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:50:29**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Yes (Y)'	Tiffany Nemecek (b) (4)	22 Sep 2020 03:58:57

**US3002122**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:50:29**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '21 Aug 2020'	Tiffany Nemecek (b) (4)	22 Sep 2020 03:58:57

**US3002122**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:50:29**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Contact Made (CONTACT MADE)'	Tiffany Nemecek (b) (4)	22 Sep 2020 03:58:57

**US3002122**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:50:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4)	
	Tiffany Nemecek (b) (4)	22 Sep 2020 03:58:57
	(b) (4)	



**US3002122**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:50:29**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Yes (Y)'	Tiffany Nemecek (b) (4)	04 Sep 2020 14:35:42

**US3002122**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:50:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:18:34
User entered 'I'	System	04 Sep 2020 14:35:42

**US3002122**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:50:29**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:05:38
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 15:49:44

**US3002122**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:50:29**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:05:38
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '28 Aug 2020'	(b) (4), (b) (6)	04 Sep 2020 15:49:44

**US3002122**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:50:29**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:05:38
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	04 Sep 2020 15:49:44

**US3002122**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:50:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:05:38
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:49:44

**US3002122**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:50:29**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:05:38
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Yes (Y)'	Tiffany Nemecek (b) (4)	04 Sep 2020 14:35:48

**US3002122**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:50:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:05:38
User entered 'I'	System	04 Sep 2020 14:35:48



**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:50:29**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 15:50:06

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:50:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '04 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:50:06

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:50:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	04 Sep 2020 15:50:06

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:50:29**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User entered 'VISIT2'	System	04 Sep 2020 15:50:06

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	04 Sep 2020 15:51:08

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:51:08

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:50:29**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '04 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 15:51:08

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:50:29**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '08:38'	(b) (4), (b) (6)	04 Sep 2020 15:51:08



**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User entered '04 Sep 2020 08:38'	System	04 Sep 2020 15:51:08

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '36.6' C	(b) (4), (b) (6)	04 Sep 2020 15:51:08

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered 'Oral (Oral)'	(b) (4), (b) (6)	04 Sep 2020 15:51:08

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:50:29**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:51:08

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '80'	(b) (4), (b) (6)	04 Sep 2020 15:51:08

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User entered 'bpm'	System	04 Sep 2020 15:51:08

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '16'	(b) (4), (b) (6)	04 Sep 2020 15:51:08

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User entered 'breaths/min'	System	04 Sep 2020 15:51:08



**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '119'	(b) (4), (b) (6)	04 Sep 2020 15:51:08

US3002122

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:50:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User entered 'mmHg'	System	04 Sep 2020 15:51:08

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '81'	(b) (4), (b) (6)	04 Sep 2020 15:51:08

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User entered 'mmHg'	System	04 Sep 2020 15:51:08

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	04 Sep 2020 15:51:08

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:51:08

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:50:29**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '04 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 15:51:08

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:50:29**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '09:56'	(b) (4), (b) (6)	04 Sep 2020 15:51:08



**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User entered '04 Sep 2020 09:56'	System	04 Sep 2020 15:51:08

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '36.8' C	(b) (4), (b) (6)	04 Sep 2020 15:51:08

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered 'Oral (Oral)'	(b) (4), (b) (6)	04 Sep 2020 15:51:08

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:50:29**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:51:08

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '82'	(b) (4), (b) (6)	04 Sep 2020 15:51:08

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User entered 'bpm'	System	04 Sep 2020 15:51:08

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '16'	(b) (4), (b) (6)	04 Sep 2020 15:51:08

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User entered 'breaths/min'	System	04 Sep 2020 15:51:08



**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '106'	(b) (4), (b) (6)	04 Sep 2020 15:51:08

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User entered 'mmHg'	System	04 Sep 2020 15:51:08

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '74'	(b) (4), (b) (6)	04 Sep 2020 15:51:08

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User entered 'mmHg'	System	04 Sep 2020 15:51:08

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:50:29**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 15:51:26

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:50:29**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '04 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:51:26

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:50:29**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 15:51:33

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:50:29**

**Date of test** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '04 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:51:33



**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:50:29**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:51:33

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:50:29**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:51:33

US3002122

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 21:50:29

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User closed query 'Per CDM: Per CCGs, a "Yes" or "No" should be selected for "Was FSH sample collected?". If "Yes", provide the collection date and time. Please update as appropriate.	(b) (4)	28 Oct 2020 11:01:03
' (Site from DM).	(b) (4), (b) (6)	
Query 'Per CDM: Per CCGs, a "Yes" or "No" should be selected for "Was FSH sample collected?". If "Yes", provide the collection date and time. Please update as appropriate.	Jessica Satorie (b) (4)	27 Oct 2020 16:37:11
' answered with 'updated' (Site from DM).	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jessica Satorie (b) (4)	27 Oct 2020 16:37:06
User opened query 'Per CDM: Per CCGs, a "Yes" or "No" should be selected for "Was FSH sample collected?". If "Yes", provide the collection date and time. Please update as appropriate.	(b) (4)	
' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 14:05:13
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:51:33

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:50:29**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:51:33

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:50:29**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:51:33

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 21:50:29**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User entered empty.	System	04 Sep 2020 15:51:33

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:50:29**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered 'Yes (Y)'	(b) (4) Tiffany Nemecek (b) (4)	04 Sep 2020 14:36:06

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:50:29**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered empty.	Tiffany Nemecek (b) (4)	04 Sep 2020 14:36:06



US3002122

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered empty.	Tiffany Nemecek (b) (4)	04 Sep 2020 14:36:06

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:50:29**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 14:36:06

US3002122

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '04 Sep 2020'	Tiffany Nemecek (b) (4)	04 Sep 2020 14:36:06

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:50:29**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '09:22'	Tiffany Nemecek (b) (4)	04 Sep 2020 14:36:06

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:50:29**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User entered '04 Sep 2020 09:22'	System	04 Sep 2020 14:36:06

US3002122

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:50:29

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered 'Left Arm (LEFT ARM)'	Tiffany Nemecek (b) (4)	04 Sep 2020 14:36:06

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:50:29**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User entered 'ONCE'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:50:29**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 14:36:06



**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:50:29**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 15:51:54

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:50:29**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '04 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 15:51:54

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:50:29**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '08:57'	(b) (4), (b) (6)	04 Sep 2020 15:51:54

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:50:29**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User entered '04 Sep 2020 08:57'	System	04 Sep 2020 15:51:54

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 11 Aug 2021 21:50:29**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '04 Sep 2020'	(b) (4), (b) (6)	04 Sep 2020 15:52:16

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	04 Sep 2020 15:52:16

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 15:52:16

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '08:48'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:52:16



**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User entered '04 Sep 2020 08:48'	System	04 Sep 2020 15:52:16

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	04 Sep 2020 15:52:16

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 15:52:16

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:50:29**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:52:16

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User entered empty.	System	04 Sep 2020 15:52:16

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:50:29**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:52:31

**US3002122**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:50:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User entered 'I'	System	04 Sep 2020 15:52:31

US3002122

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	04 Sep 2020 14:36:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 14:36:06



US3002122

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-04T09:48:08', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '1004ac6c-7c31-46f6-872c-c47d7b07045c'	System	04 Sep 2020 14:48:20
User entered 'Yes (Y)'	System	04 Sep 2020 14:48:20

US3002122

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-04T09:48:12', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '1004ac6c-7c31-46f6-872c-c47d7b07045c'	System	04 Sep 2020 14:48:20
User entered '98.3'	System	04 Sep 2020 14:48:20

US3002122

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-04T09:48:15', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '1004ac6c-7c31-46f6-872c-c47d7b07045c'	System	04 Sep 2020 14:48:20
User entered 'No (N)'	System	04 Sep 2020 14:48:20

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-04T09:48:17', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '1004ac6c-7c31-46f6-872c-c47d7b07045c'	System	04 Sep 2020 14:48:20
User entered '04 Sep 2020 09:48'	System	04 Sep 2020 14:48:20

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '04 Sep 2020 09:42'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '04 Sep 2020 12:12'	System	04 Sep 2020 14:36:06

US3002122

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	04 Sep 2020 14:36:06
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 14:36:06

US3002122

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-05T11:50:20', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'c8ad96e3-9dda-4bfa-9666-5e37022be26a'	System	05 Sep 2020 16:50:34
User entered 'Yes (Y)'	System	05 Sep 2020 16:50:34



US3002122

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-05T11:50:25', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'c8ad96e3-9dda-4bfa-9666-5e37022be26a'	System	05 Sep 2020 16:50:34
User entered '98.3'	System	05 Sep 2020 16:50:34

US3002122

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-05T11:50:28', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'c8ad96e3-9dda-4bfa-9666-5e37022be26a'	System	05 Sep 2020 16:50:34
User entered 'No (N)'	System	05 Sep 2020 16:50:34

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-05T11:50:30', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'c8ad96e3-9dda-4bfa-9666-5e37022be26a'	System	05 Sep 2020 16:50:34
User entered '05 Sep 2020 11:50'	System	05 Sep 2020 16:50:34

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '04 Sep 2020 13:07'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	04 Sep 2020 14:36:06
User entered 'Day 2'	System	04 Sep 2020 14:36:06

US3002122

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:50:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-05T12:09:18', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '65217f42-2244-42ce-bc11-b181a7e80a2c'	System	05 Sep 2020 17:09:28
User entered 'Yes (Y)'	System	05 Sep 2020 17:09:28

US3002122

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:50:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-05T12:09:21', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '65217f42-2244-42ce-bc11-b181a7e80a2c'	System	05 Sep 2020 17:09:28
User entered '98.4'	System	05 Sep 2020 17:09:28



US3002122

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-05T12:09:24', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '65217f42-2244-42ce-bc11-b181a7e80a2c'	System	05 Sep 2020 17:09:28
User entered 'No (N)'	System	05 Sep 2020 17:09:28

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-05T12:09:25', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '65217f42-2244-42ce-bc11-b181a7e80a2c'	System	05 Sep 2020 17:09:28
User entered '05 Sep 2020 12:09'	System	05 Sep 2020 17:09:28

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 14:36:06

US3002122

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	04 Sep 2020 14:36:06
User entered 'Day 3'	System	04 Sep 2020 14:36:06

US3002122

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:50:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-07T09:44:34', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'd477f98e-9549-4385-bf5a-d58ef4329e41'	System	07 Sep 2020 14:44:56
User entered 'Yes (Y)'	System	07 Sep 2020 14:44:56

US3002122

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:50:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-07T09:44:47', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'd477f98e-9549-4385-bf5a-d58ef4329e41'	System	07 Sep 2020 14:44:56
User entered '98.5'	System	07 Sep 2020 14:44:56

US3002122

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-07T09:44:51', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'd477f98e-9549-4385-bf5a-d58ef4329e41'	System	07 Sep 2020 14:44:56
User entered 'No (N)'	System	07 Sep 2020 14:44:56



**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-07T09:44:53', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'd477f98e-9549-4385-bf5a-d58ef4329e41'	System	07 Sep 2020 14:44:56
User entered '07 Sep 2020 09:44'	System	07 Sep 2020 14:44:56

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	04 Sep 2020 14:36:06
User entered 'Day 4'	System	04 Sep 2020 14:36:06

US3002122

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:50:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-07T18:12:57', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '40e326a6-cd26-49dc-ba9d-4504d993d4b8'	System	07 Sep 2020 23:13:10
User entered 'Yes (Y)'	System	07 Sep 2020 23:13:10

US3002122

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:50:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-07T18:13:01', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '40e326a6-cd26-49dc-ba9d-4504d993d4b8'	System	07 Sep 2020 23:13:10
User entered '97.3'	System	07 Sep 2020 23:13:10

US3002122

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-07T18:13:04', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '40e326a6-cd26-49dc-ba9d-4504d993d4b8'	System	07 Sep 2020 23:13:10
User entered 'No (N)'	System	07 Sep 2020 23:13:10

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-07T18:13:06', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '40e326a6-cd26-49dc-ba9d-4504d993d4b8'	System	07 Sep 2020 23:13:10
User entered '07 Sep 2020 18:13'	System	07 Sep 2020 23:13:10



**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	04 Sep 2020 14:36:06
User entered 'Day 5'	System	04 Sep 2020 14:36:06

US3002122

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:50:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-08T17:31:23', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'eb0e98f9-1003-48a4-9565-4793b52a0577'	System	08 Sep 2020 22:33:25
User entered 'Yes (Y)'	System	08 Sep 2020 22:33:25

US3002122

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:50:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-08T17:33:18', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'eb0e98f9-1003-48a4-9565-4793b52a0577'	System	08 Sep 2020 22:33:25
User entered '98.0'	System	08 Sep 2020 22:33:25

US3002122

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-08T17:33:20', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'eb0e98f9-1003-48a4-9565-4793b52a0577'	System	08 Sep 2020 22:33:25
User entered 'No (N)'	System	08 Sep 2020 22:33:25

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-08T17:33:22', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'eb0e98f9-1003-48a4-9565-4793b52a0577'	System	08 Sep 2020 22:33:25
User entered '08 Sep 2020 17:33'	System	08 Sep 2020 22:33:25

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 14:36:06



**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 14:36:06

US3002122

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	04 Sep 2020 14:36:06
User entered 'Day 6'	System	04 Sep 2020 14:36:06

US3002122

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:50:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-09T12:00:23', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'ff4782c4-0118-4c7c-9c5c-673878830fe9'	System	09 Sep 2020 18:00:40
User entered 'Yes (Y)'	System	09 Sep 2020 18:00:40

US3002122

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:50:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-09T12:00:31', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'ff4782c4-0118-4c7c-9c5c-673878830fe9'	System	09 Sep 2020 18:00:40
User entered '97.6'	System	09 Sep 2020 18:00:40

US3002122

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-09T12:00:34', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'ff4782c4-0118-4c7c-9c5c-673878830fe9'	System	09 Sep 2020 18:00:40
User entered 'No (N)'	System	09 Sep 2020 18:00:40

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-09T12:00:36', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'ff4782c4-0118-4c7c-9c5c-673878830fe9'	System	09 Sep 2020 18:00:40
User entered '09 Sep 2020 12:00'	System	09 Sep 2020 18:00:40

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 14:36:06



US3002122

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	04 Sep 2020 14:36:06
User entered 'Day 7'	System	04 Sep 2020 14:36:06

US3002122

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:50:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-10T12:31:14', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '51fa83f6-f7cc-4e4c-afc5-e02976325273'	System	10 Sep 2020 18:31:24
User entered 'Yes (Y)'	System	10 Sep 2020 18:31:24

US3002122

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:50:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-10T12:31:17', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '51fa83f6-f7cc-4e4c-afc5-e02976325273'	System	10 Sep 2020 18:31:24
User entered '98.7'	System	10 Sep 2020 18:31:24

US3002122

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-10T12:31:19', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '51fa83f6-f7cc-4e4c-afc5-e02976325273'	System	10 Sep 2020 18:31:24
User entered 'No (N)'	System	10 Sep 2020 18:31:24

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-10T12:31:21', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '51fa83f6-f7cc-4e4c-afc5-e02976325273'	System	10 Sep 2020 18:31:24
User entered '10 Sep 2020 12:31'	System	10 Sep 2020 18:31:24

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 14:36:06

US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	04 Sep 2020 14:36:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 14:36:06



US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-04T09:48:29', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '6ab33e69-3536-42fa-aed7-eaa17bb721ed'	System	04 Sep 2020 14:48:41
User entered 'None (1)'	System	04 Sep 2020 14:48:41

US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-04T09:48:31', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '6ab33e69-3536-42fa-aed7-eaa17bb721ed'	System	04 Sep 2020 14:48:41
User entered 'No (N)'	System	04 Sep 2020 14:48:41

US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-04T09:48:33', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '6ab33e69-3536-42fa-aed7-eaa17bb721ed'	System	04 Sep 2020 14:48:41
User entered 'No (N)'	System	04 Sep 2020 14:48:41

US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-04T09:48:37', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '6ab33e69-3536-42fa-aed7-eaa17bb721ed'	System	04 Sep 2020 14:48:41
User entered 'None (1)'	System	04 Sep 2020 14:48:41

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-04T09:48:39', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '6ab33e69-3536-42fa-aed7-eaa17bb721ed'	System	04 Sep 2020 14:48:41
User entered '04 Sep 2020 09:48'	System	04 Sep 2020 14:48:41

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '04 Sep 2020 09:42'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '04 Sep 2020 12:12'	System	04 Sep 2020 14:36:06

US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	04 Sep 2020 14:36:06
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 14:36:06



US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-05T11:50:34', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'db0a5657-22a6-4190-907d-2bdfa271fa8c'	System	05 Sep 2020 16:50:45
User entered 'None (1)'	System	05 Sep 2020 16:50:45

US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-05T11:50:37', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'db0a5657-22a6-4190-907d-2bdfa271fa8c'	System	05 Sep 2020 16:50:45
User entered 'No (N)'	System	05 Sep 2020 16:50:45

US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-05T11:50:39', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'db0a5657-22a6-4190-907d-2bdfa271fa8c'	System	05 Sep 2020 16:50:45
User entered 'No (N)'	System	05 Sep 2020 16:50:45

US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-05T11:50:41', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'db0a5657-22a6-4190-907d-2bdfa271fa8c'	System	05 Sep 2020 16:50:45
User entered 'None (1)'	System	05 Sep 2020 16:50:45

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-05T11:50:42', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'db0a5657-22a6-4190-907d-2bdfa271fa8c'	System	05 Sep 2020 16:50:45
User entered '05 Sep 2020 11:50'	System	05 Sep 2020 16:50:45

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '04 Sep 2020 13:07'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	04 Sep 2020 14:36:06
User entered 'Day 2'	System	04 Sep 2020 14:36:06



US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-05T12:09:29', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '99005d76-1bf8-4079-bbce-71e0b765175c'	System	05 Sep 2020 17:09:42
User entered 'None (1)'	System	05 Sep 2020 17:09:42

US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:50:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-05T12:09:33', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '99005d76-1bf8-4079-bbce-71e0b765175c'	System	05 Sep 2020 17:09:42
User entered 'No (N)'	System	05 Sep 2020 17:09:42

US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-05T12:09:35', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '99005d76-1bf8-4079-bbce-71e0b765175c'	System	05 Sep 2020 17:09:42
User entered 'No (N)'	System	05 Sep 2020 17:09:42

US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-05T12:09:37', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '99005d76-1bf8-4079-bbce-71e0b765175c'	System	05 Sep 2020 17:09:42
User entered 'None (1)'	System	05 Sep 2020 17:09:42

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-05T12:09:39', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '99005d76-1bf8-4079-bbce-71e0b765175c'	System	05 Sep 2020 17:09:42
User entered '05 Sep 2020 12:09'	System	05 Sep 2020 17:09:42

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	04 Sep 2020 14:36:06
User entered 'Day 3'	System	04 Sep 2020 14:36:06



US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-06T12:01:50', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '0f048097-0c42-4120-9f97-5d1ec51c9aea'	System	06 Sep 2020 17:02:32
User entered 'None (1)'	System	06 Sep 2020 17:02:32

US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:50:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-06T12:01:52', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '0f048097-0c42-4120-9f97-5d1ec51c9aea'	System	06 Sep 2020 17:02:32
User entered 'No (N)'	System	06 Sep 2020 17:02:32

US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-06T12:01:54', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '0f048097-0c42-4120-9f97-5d1ec51c9aea'	System	06 Sep 2020 17:02:32
User entered 'No (N)'	System	06 Sep 2020 17:02:32

US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-06T12:01:58', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '0f048097-0c42-4120-9f97-5d1ec51c9aea'	System	06 Sep 2020 17:02:32
User entered 'None (1)'	System	06 Sep 2020 17:02:32

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-06T12:01:59', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '0f048097-0c42-4120-9f97-5d1ec51c9aea'	System	06 Sep 2020 17:02:32
User entered '06 Sep 2020 12:01'	System	06 Sep 2020 17:02:32

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 14:36:06

US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:50:29

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	04 Sep 2020 14:36:06
User entered 'Day 4'	System	04 Sep 2020 14:36:06



US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-07T14:28:31', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'e04f611b-8523-474e-9e0e-1ff6ab7682de'	System	07 Sep 2020 19:28:47
User entered 'None (1)'	System	07 Sep 2020 19:28:47

US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:50:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-07T14:28:35', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'e04f611b-8523-474e-9e0e-1ff6ab7682de'	System	07 Sep 2020 19:28:47
User entered 'No (N)'	System	07 Sep 2020 19:28:47

US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-07T14:28:38', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'e04f611b-8523-474e-9e0e-1ff6ab7682de'	System	07 Sep 2020 19:28:47
User entered 'No (N)'	System	07 Sep 2020 19:28:47

US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-07T14:28:40', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'e04f611b-8523-474e-9e0e-1ff6ab7682de'	System	07 Sep 2020 19:28:47
User entered 'None (1)'	System	07 Sep 2020 19:28:47

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-07T14:28:43', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'e04f611b-8523-474e-9e0e-1ff6ab7682de'	System	07 Sep 2020 19:28:47
User entered '07 Sep 2020 14:28'	System	07 Sep 2020 19:28:47

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	04 Sep 2020 14:36:06
User entered 'Day 5'	System	04 Sep 2020 14:36:06



US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-08T17:30:50', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '85268b82-e4f6-4ee7-8707-2dd120bacdac'	System	08 Sep 2020 22:31:00
User entered 'None (1)'	System	08 Sep 2020 22:31:00

US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:50:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-08T17:30:52', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '85268b82-e4f6-4ee7-8707-2dd120bacdac'	System	08 Sep 2020 22:31:00
User entered 'No (N)'	System	08 Sep 2020 22:31:00

US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-08T17:30:53', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '85268b82-e4f6-4ee7-8707-2dd120bacdac'	System	08 Sep 2020 22:31:00
User entered 'No (N)'	System	08 Sep 2020 22:31:00

US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-08T17:30:55', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '85268b82-e4f6-4ee7-8707-2dd120bacdac'	System	08 Sep 2020 22:31:00
User entered 'None (1)'	System	08 Sep 2020 22:31:00

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-08T17:30:57', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '85268b82-e4f6-4ee7-8707-2dd120bacdac'	System	08 Sep 2020 22:31:00
User entered '08 Sep 2020 17:30'	System	08 Sep 2020 22:31:00

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	04 Sep 2020 14:36:06
User entered 'Day 6'	System	04 Sep 2020 14:36:06



US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-09T12:00:39', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '2710d379-0d89-4e36-ae97-fe6932899b73'	System	09 Sep 2020 18:00:54
User entered 'None (1)'	System	09 Sep 2020 18:00:54

US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:50:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-09T12:00:41', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '2710d379-0d89-4e36-ae97-fe6932899b73'	System	09 Sep 2020 18:00:54
User entered 'No (N)'	System	09 Sep 2020 18:00:54

US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-09T12:00:46', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '2710d379-0d89-4e36-ae97-fe6932899b73'	System	09 Sep 2020 18:00:54
User entered 'No (N)'	System	09 Sep 2020 18:00:54

US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-09T12:00:48', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '2710d379-0d89-4e36-ae97-fe6932899b73'	System	09 Sep 2020 18:00:54
User entered 'None (1)'	System	09 Sep 2020 18:00:54

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-09T12:00:50', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '2710d379-0d89-4e36-ae97-fe6932899b73'	System	09 Sep 2020 18:00:54
User entered '09 Sep 2020 12:00'	System	09 Sep 2020 18:00:54

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	04 Sep 2020 14:36:06
User entered 'Day 7'	System	04 Sep 2020 14:36:06



US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-10T12:31:38', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'd35cb1da-adeb-48f5-88d2-acf673c53dc4'	System	10 Sep 2020 18:31:50
User entered 'None (1)'	System	10 Sep 2020 18:31:50

US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:50:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-10T12:31:40', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'd35cb1da-adeb-48f5-88d2-acf673c53dc4'	System	10 Sep 2020 18:31:50
User entered 'No (N)'	System	10 Sep 2020 18:31:50

US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:50:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-10T12:31:43', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'd35cb1da-adeb-48f5-88d2-acf673c53dc4'	System	10 Sep 2020 18:31:50
User entered 'No (N)'	System	10 Sep 2020 18:31:50

US3002122

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:50:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-10T12:31:44', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'd35cb1da-adeb-48f5-88d2-acf673c53dc4'	System	10 Sep 2020 18:31:50
User entered 'None (1)'	System	10 Sep 2020 18:31:50

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-10T12:31:46', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'd35cb1da-adeb-48f5-88d2-acf673c53dc4'	System	10 Sep 2020 18:31:50
User entered '10 Sep 2020 12:31'	System	10 Sep 2020 18:31:50

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	04 Sep 2020 14:36:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 14:36:06



**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:50:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-04T09:48:45', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'd2c041c3-4896-4a72-85b9-71f15a7db9a3'	System	04 Sep 2020 14:49:09
User entered 'None (0)'	System	04 Sep 2020 14:49:09

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:50:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-04T09:48:48', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'd2c041c3-4896-4a72-85b9-71f15a7db9a3'	System	04 Sep 2020 14:49:09
User entered 'None (0)'	System	04 Sep 2020 14:49:09

US3002122

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-04T09:48:50', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'd2c041c3-4896-4a72-85b9-71f15a7db9a3'	System	04 Sep 2020 14:49:09
User entered 'None (0)'	System	04 Sep 2020 14:49:09

US3002122

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-04T09:48:53', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'd2c041c3-4896-4a72-85b9-71f15a7db9a3'	System	04 Sep 2020 14:49:09
User entered 'None (0)'	System	04 Sep 2020 14:49:09

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:50:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-04T09:48:55', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'd2c041c3-4896-4a72-85b9-71f15a7db9a3'	System	04 Sep 2020 14:49:09
User entered 'None (0)'	System	04 Sep 2020 14:49:09

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:50:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-04T09:48:57', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'd2c041c3-4896-4a72-85b9-71f15a7db9a3'	System	04 Sep 2020 14:49:09
User entered 'None (0)'	System	04 Sep 2020 14:49:09

US3002122

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:50:29

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)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-04T09:49:01', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'd2c041c3-4896-4a72-85b9-71f15a7db9a3'	System	04 Sep 2020 14:49:09
User entered 'No (N)'	System	04 Sep 2020 14:49:09

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-04T09:49:03', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'd2c041c3-4896-4a72-85b9-71f15a7db9a3'	System	04 Sep 2020 14:49:09
User entered '04 Sep 2020 09:49'	System	04 Sep 2020 14:49:09



**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '04 Sep 2020 09:42'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '04 Sep 2020 12:12'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	04 Sep 2020 14:36:06
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:50:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-05T11:50:46', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '8d103684-f680-4c8e-b1ba-6d141cdb3df9'	System	05 Sep 2020 16:51:00
User entered 'None (0)'	System	05 Sep 2020 16:51:00

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:50:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-05T11:50:48', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '8d103684-f680-4c8e-b1ba-6d141cdb3df9'	System	05 Sep 2020 16:51:00
User entered 'None (0)'	System	05 Sep 2020 16:51:00

US3002122

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-05T11:50:50', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '8d103684-f680-4c8e-b1ba-6d141cdb3df9'	System	05 Sep 2020 16:51:00
User entered 'None (0)'	System	05 Sep 2020 16:51:00

US3002122

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-05T11:50:51', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '8d103684-f680-4c8e-b1ba-6d141cdb3df9'	System	05 Sep 2020 16:51:00
User entered 'None (0)'	System	05 Sep 2020 16:51:00

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:50:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-05T11:50:52', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '8d103684-f680-4c8e-b1ba-6d141cdb3df9'	System	05 Sep 2020 16:51:00
User entered 'None (0)'	System	05 Sep 2020 16:51:00



**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:50:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-05T11:50:53', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '8d103684-f680-4c8e-b1ba-6d141cdb3df9'	System	05 Sep 2020 16:51:00
User entered 'None (0)'	System	05 Sep 2020 16:51:00

US3002122

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:50:29

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)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-05T11:50:56', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '8d103684-f680-4c8e-b1ba-6d141cdb3df9'	System	05 Sep 2020 16:51:00
User entered 'No (N)'	System	05 Sep 2020 16:51:00

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-05T11:50:58', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '8d103684-f680-4c8e-b1ba-6d141cdb3df9'	System	05 Sep 2020 16:51:00
User entered '05 Sep 2020 11:50'	System	05 Sep 2020 16:51:00

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '04 Sep 2020 13:07'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	04 Sep 2020 14:36:06
User entered 'Day 2'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:50:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-05T12:09:43', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '9c80a09c-a6fe-4b0a-a9eb-ed9a3afab3fb'	System	05 Sep 2020 17:10:03
User entered 'None (0)'	System	05 Sep 2020 17:10:03

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:50:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-05T12:09:46', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '9c80a09c-a6fe-4b0a-a9eb-ed9a3afab3fb'	System	05 Sep 2020 17:10:03
User entered 'None (0)'	System	05 Sep 2020 17:10:03



US3002122

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:50:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-05T12:09:47', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '9c80a09c-a6fe-4b0a-a9eb-ed9a3afab3fb'	System	05 Sep 2020 17:10:03
User entered 'None (0)'	System	05 Sep 2020 17:10:03

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:50:29**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-05T12:09:49', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '9c80a09c-a6fe-4b0a-a9eb-ed9a3afab3fb'	System	05 Sep 2020 17:10:03
User entered 'None (0)'	System	05 Sep 2020 17:10:03

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:50:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-05T12:09:52', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '9c80a09c-a6fe-4b0a-a9eb-ed9a3afab3fb'	System	05 Sep 2020 17:10:03
User entered 'None (0)'	System	05 Sep 2020 17:10:03

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:50:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-05T12:09:54', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '9c80a09c-a6fe-4b0a-a9eb-ed9a3afab3fb'	System	05 Sep 2020 17:10:03
User entered 'None (0)'	System	05 Sep 2020 17:10:03

US3002122

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:50:29

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)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-05T12:09:56', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '9c80a09c-a6fe-4b0a-a9eb-ed9a3afab3fb'	System	05 Sep 2020 17:10:03
User entered 'No (N)'	System	05 Sep 2020 17:10:03

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-05T12:09:58', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '9c80a09c-a6fe-4b0a-a9eb-ed9a3afab3fb'	System	05 Sep 2020 17:10:03
User entered '05 Sep 2020 12:09'	System	05 Sep 2020 17:10:03

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 14:36:06



**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	04 Sep 2020 14:36:06
User entered 'Day 3'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:50:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-06T12:02:13', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '8c2a3c00-3a22-4e06-8337-6c0418037803'	System	06 Sep 2020 17:05:32
User entered 'No interference with activity (1)'	System	06 Sep 2020 17:05:32

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:50:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-06T12:02:18', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '8c2a3c00-3a22-4e06-8337-6c0418037803'	System	06 Sep 2020 17:05:32
User entered 'None (0)'	System	06 Sep 2020 17:05:32

US3002122

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:50:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-06T12:02:24', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '8c2a3c00-3a22-4e06-8337-6c0418037803'	System	06 Sep 2020 17:05:32
User entered 'None (0)'	System	06 Sep 2020 17:05:32

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:50:29**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-06T12:02:26', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '8c2a3c00-3a22-4e06-8337-6c0418037803'	System	06 Sep 2020 17:05:32
User entered 'None (0)'	System	06 Sep 2020 17:05:32

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:50:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-06T12:02:28', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '8c2a3c00-3a22-4e06-8337-6c0418037803'	System	06 Sep 2020 17:05:32
User entered 'None (0)'	System	06 Sep 2020 17:05:32

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:50:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-06T12:02:31', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '8c2a3c00-3a22-4e06-8337-6c0418037803'	System	06 Sep 2020 17:05:32
User entered 'None (0)'	System	06 Sep 2020 17:05:32

US3002122

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:50:29

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)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-06T12:05:27', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '8c2a3c00-3a22-4e06-8337-6c0418037803'	System	06 Sep 2020 17:05:32
User entered 'No (N)'	System	06 Sep 2020 17:05:32



**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-06T12:05:28', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '8c2a3c00-3a22-4e06-8337-6c0418037803'	System	06 Sep 2020 17:05:32
User entered '06 Sep 2020 12:05'	System	06 Sep 2020 17:05:32

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	04 Sep 2020 14:36:06
User entered 'Day 4'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:50:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-07T14:28:52', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '76028e7c-f19c-4213-8a5f-ba88ca1ac6bd'	System	07 Sep 2020 19:29:08
User entered 'No interference with activity (1)'	System	07 Sep 2020 19:29:08

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:50:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-07T14:28:54', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '76028e7c-f19c-4213-8a5f-ba88ca1ac6bd'	System	07 Sep 2020 19:29:08
User entered 'None (0)'	System	07 Sep 2020 19:29:08

US3002122

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:50:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-07T14:28:55', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '76028e7c-f19c-4213-8a5f-ba88ca1ac6bd'	System	07 Sep 2020 19:29:08
User entered 'None (0)'	System	07 Sep 2020 19:29:08

US3002122

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:50:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-07T14:28:57', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '76028e7c-f19c-4213-8a5f-ba88ca1ac6bd'	System	07 Sep 2020 19:29:08
User entered 'None (0)'	System	07 Sep 2020 19:29:08



**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:50:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-07T14:28:59', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '76028e7c-f19c-4213-8a5f-ba88ca1ac6bd'	System	07 Sep 2020 19:29:08
User entered 'None (0)'	System	07 Sep 2020 19:29:08

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:50:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-07T14:29:02', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '76028e7c-f19c-4213-8a5f-ba88ca1ac6bd'	System	07 Sep 2020 19:29:08
User entered 'None (0)'	System	07 Sep 2020 19:29:08

US3002122

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:50:29

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)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-07T14:29:05', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '76028e7c-f19c-4213-8a5f-ba88ca1ac6bd'	System	07 Sep 2020 19:29:08
User entered 'No (N)'	System	07 Sep 2020 19:29:08

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-07T14:29:06', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '76028e7c-f19c-4213-8a5f-ba88ca1ac6bd'	System	07 Sep 2020 19:29:08
User entered '07 Sep 2020 14:29'	System	07 Sep 2020 19:29:08

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	04 Sep 2020 14:36:06
User entered 'Day 5'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:50:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-08T17:31:01', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'cef2401a-a9bf-46f4-8e73-3d9f5e5a95f6'	System	08 Sep 2020 22:31:15
User entered 'None (0)'	System	08 Sep 2020 22:31:15



**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:50:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-08T17:31:03', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'cef2401a-a9bf-46f4-8e73-3d9f5e5a95f6'	System	08 Sep 2020 22:31:15
User entered 'None (0)'	System	08 Sep 2020 22:31:15

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:50:29**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-08T17:31:05', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'cef2401a-a9bf-46f4-8e73-3d9f5e5a95f6'	System	08 Sep 2020 22:31:15
User entered 'None (0)'	System	08 Sep 2020 22:31:15

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:50:29**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-08T17:31:07', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'cef2401a-a9bf-46f4-8e73-3d9f5e5a95f6'	System	08 Sep 2020 22:31:15
User entered 'None (0)'	System	08 Sep 2020 22:31:15

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:50:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-08T17:31:08', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'cef2401a-a9bf-46f4-8e73-3d9f5e5a95f6'	System	08 Sep 2020 22:31:15
User entered 'None (0)'	System	08 Sep 2020 22:31:15

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:50:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-08T17:31:10', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'cef2401a-a9bf-46f4-8e73-3d9f5e5a95f6'	System	08 Sep 2020 22:31:15
User entered 'No interference with activity (1)'	System	08 Sep 2020 22:31:15

US3002122

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:50:29

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)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-08T17:31:12', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'cef2401a-a9bf-46f4-8e73-3d9f5e5a95f6'	System	08 Sep 2020 22:31:15
User entered 'No (N)'	System	08 Sep 2020 22:31:15

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-08T17:31:14', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'cef2401a-a9bf-46f4-8e73-3d9f5e5a95f6'	System	08 Sep 2020 22:31:15
User entered '08 Sep 2020 17:31'	System	08 Sep 2020 22:31:15

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 14:36:06



**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	04 Sep 2020 14:36:06
User entered 'Day 6'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:50:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-09T12:00:55', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '6813977e-2af6-47a8-82ae-1725888ba318'	System	09 Sep 2020 18:01:24
User entered 'No interference with activity (1)'	System	09 Sep 2020 18:01:24

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:50:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-09T12:00:57', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '6813977e-2af6-47a8-82ae-1725888ba318'	System	09 Sep 2020 18:01:24
User entered 'None (0)'	System	09 Sep 2020 18:01:24

US3002122

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:50:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-09T12:01:00', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '6813977e-2af6-47a8-82ae-1725888ba318'	System	09 Sep 2020 18:01:24
User entered 'None (0)'	System	09 Sep 2020 18:01:24

US3002122

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:50:29

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-09T12:01:06', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '6813977e-2af6-47a8-82ae-1725888ba318'	System	09 Sep 2020 18:01:24
User entered 'None (0)'	System	09 Sep 2020 18:01:24

US3002122

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:50:29

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-09T12:01:12', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '6813977e-2af6-47a8-82ae-1725888ba318'	System	09 Sep 2020 18:01:24
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	09 Sep 2020 18:01:24

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:50:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-09T12:01:14', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '6813977e-2af6-47a8-82ae-1725888ba318'	System	09 Sep 2020 18:01:24
User entered 'None (0)'	System	09 Sep 2020 18:01:24



US3002122

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:50:29

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)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-09T12:01:16', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '6813977e-2af6-47a8-82ae-1725888ba318'	System	09 Sep 2020 18:01:24
User entered 'No (N)'	System	09 Sep 2020 18:01:24

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-09T12:01:18', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '6813977e-2af6-47a8-82ae-1725888ba318'	System	09 Sep 2020 18:01:24
User entered '09 Sep 2020 12:01'	System	09 Sep 2020 18:01:24

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	04 Sep 2020 14:36:06
User entered 'Day 7'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:50:29**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-10T12:31:24', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '2e699cc0-6c89-4e36-b942-ef778bf678ca'	System	10 Sep 2020 18:31:38
User entered 'None (0)'	System	10 Sep 2020 18:31:38

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:50:29**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-10T12:31:26', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '2e699cc0-6c89-4e36-b942-ef778bf678ca'	System	10 Sep 2020 18:31:38
User entered 'None (0)'	System	10 Sep 2020 18:31:38

US3002122

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:50:29

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-10T12:31:27', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '2e699cc0-6c89-4e36-b942-ef778bf678ca'	System	10 Sep 2020 18:31:38
User entered 'None (0)'	System	10 Sep 2020 18:31:38



**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:50:29**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-10T12:31:28', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '2e699cc0-6c89-4e36-b942-ef778bf678ca'	System	10 Sep 2020 18:31:38
User entered 'None (0)'	System	10 Sep 2020 18:31:38

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:50:29**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-10T12:31:29', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '2e699cc0-6c89-4e36-b942-ef778bf678ca'	System	10 Sep 2020 18:31:38
User entered 'None (0)'	System	10 Sep 2020 18:31:38

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:50:29**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-10T12:31:30', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '2e699cc0-6c89-4e36-b942-ef778bf678ca'	System	10 Sep 2020 18:31:38
User entered 'None (0)'	System	10 Sep 2020 18:31:38

US3002122

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:50:29

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)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-10T12:31:32', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '2e699cc0-6c89-4e36-b942-ef778bf678ca'	System	10 Sep 2020 18:31:38
User entered 'No (N)'	System	10 Sep 2020 18:31:38

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-09-10T12:31:35', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '2e699cc0-6c89-4e36-b942-ef778bf678ca'	System	10 Sep 2020 18:31:38
User entered '10 Sep 2020 12:31'	System	10 Sep 2020 18:31:38

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:50:29**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 14:36:06

**US3002122**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:50:29**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Yes (Y)'	Tiffany Nemecek (b) (4)	19 Sep 2020 15:40:01



**US3002122**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:50:29**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '14 Sep 2020'	Tiffany Nemecek (b) (4)	19 Sep 2020 15:40:01

**US3002122**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:50:29**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Contact Made (CONTACT MADE)'	Tiffany Nemecek (b) (4)	19 Sep 2020 15:40:01

**US3002122**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:50:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	Tiffany Nemecek (b) (4)	19 Sep 2020 15:40:01

**US3002122**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:50:29**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Yes (Y)'	Tiffany Nemecek (b) (4)	19 Sep 2020 15:39:50

**US3002122**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:50:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User entered 'I'	System	19 Sep 2020 15:39:50

**US3002122**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:50:29**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:53:46

**US3002122**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:50:29**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:53:46

**US3002122**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:50:29**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:53:46



**US3002122**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:50:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:53:46

**US3002122**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:50:29**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:53:50

**US3002122**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:50:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User entered 'I'	System	30 Sep 2020 14:53:50

**US3002122**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:50:29**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:54:03

**US3002122**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:50:29**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '25 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:54:03

**US3002122**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:50:29**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:54:03

**US3002122**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:50:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:54:03

**US3002122**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:50:29**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:54:06



**US3002122**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:50:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User entered 'I'	System	30 Sep 2020 14:54:06

**US3002122**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:50:29**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:54:18

**US3002122**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:50:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '30 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:54:18

**US3002122**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:50:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:54:18

**US3002122**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:50:29**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User entered 'VISIT3'	System	30 Sep 2020 14:54:18

**US3002122**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:55:02

**US3002122**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '30 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:55:02

**US3002122**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '08:03'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:55:02



**US3002122**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User entered '30 Sep 2020 08:03'	System	30 Sep 2020 14:55:02

**US3002122**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '36.6' C	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:55:02

**US3002122**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:55:02

**US3002122**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:55:02

**US3002122**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '77'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:55:02

**US3002122**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User entered 'bpm'	System	30 Sep 2020 14:55:02

**US3002122**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '12'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:55:02

**US3002122**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User entered 'breaths/min'	System	30 Sep 2020 14:55:02



**US3002122**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '112'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:55:02

**US3002122**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User entered 'mmHg'	System	30 Sep 2020 14:55:02

**US3002122**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '73'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:55:02

**US3002122**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User entered 'mmHg'	System	30 Sep 2020 14:55:02

**US3002122**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42

**US3002122**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42

**US3002122**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:50:29**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:55:11

**US3002122**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:50:29**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '30 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:55:11



**US3002122**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:50:29**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:55:24

**US3002122**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:50:29**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '30 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:55:24

**US3002122**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:50:29**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:01:05
User entered '08:25'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 14:55:24

**US3002122**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:50:29**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User entered '30 Sep 2020 08:25'	System	30 Sep 2020 14:55:24

US3002122

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:50:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 18FEB2021 is reported under OL-1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under OL-D1 Visit on Immunogenicity Assessment page.' (Site from DM). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 18FEB2021 is reported under OL-1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under OL-D1 Visit on Immunogenicity Assessment page.' answered with 'added' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 10:08:53
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 18FEB2021 is reported under OL-1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under OL-D1 Visit on Immunogenicity Assessment page.' (Site from DM). User signature succeeded.	Kimberly Mueller (b) (4) (b) (4)	24 Mar 2021 18:22:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 12:22:29
	Brandon Essink (b) (4) (b) (4)	13 Feb 2021 13:01:05
	(b) (4), (b) (6)	30 Sep 2020 14:55:27

**US3002122**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:50:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User entered 'I'	System	30 Sep 2020 14:55:27

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered 'Day 64'	System	07 Aug 2020 13:10:06

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-10-08T20:54:32', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'b839fff7-56c3-4fc8-ae83-44827e6d2662'	System	09 Oct 2020 01:54:44
User entered 'No (N)'	System	09 Oct 2020 01:54:44



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-10-08T20:54:38', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'b839fff7-56c3-4fc8-ae83-44827e6d2662'	System	09 Oct 2020 01:54:44
User entered 'No (N)'	System	09 Oct 2020 01:54:44

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-10-08T20:54:41', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'b839fff7-56c3-4fc8-ae83-44827e6d2662'	System	09 Oct 2020 01:54:44
User entered '08 Oct 2020 20:54:41'	System	09 Oct 2020 01:54:44

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered '07 Oct 2020 00:01'	System	07 Aug 2020 13:10:06

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered '11 Oct 2020 23:59'	System	07 Aug 2020 13:10:06

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered 'Day 71'	System	07 Aug 2020 13:10:06

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-10-15T14:46:00', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '0c3483d8-4dc1-4cc3-b78f-55828f977580'	System	15 Oct 2020 19:46:12
User entered 'No (N)'	System	15 Oct 2020 19:46:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-10-15T14:46:06', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '0c3483d8-4dc1-4cc3-b78f-55828f977580'	System	15 Oct 2020 19:46:12
User entered 'No (N)'	System	15 Oct 2020 19:46:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-10-15T14:46:08', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '0c3483d8-4dc1-4cc3-b78f-55828f977580'	System	15 Oct 2020 19:46:12
User entered '15 Oct 2020 14:46:08'	System	15 Oct 2020 19:46:12



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered '14 Oct 2020 00:01'	System	07 Aug 2020 13:10:06

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered '18 Oct 2020 23:59'	System	07 Aug 2020 13:10:06

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered 'Day 78'	System	07 Aug 2020 13:10:06

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-10-21T04:57:01', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'f7a04a86-07dc-415e-b060-af2fb4c5baad'	System	21 Oct 2020 09:57:21
User entered 'No (N)'	System	21 Oct 2020 09:57:21

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-10-21T04:57:08', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'f7a04a86-07dc-415e-b060-af2fb4c5baad'	System	21 Oct 2020 09:57:21
User entered 'Yes (Y)'	System	21 Oct 2020 09:57:21

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-10-21T04:57:11', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'f7a04a86-07dc-415e-b060-af2fb4c5baad'	System	21 Oct 2020 09:57:21
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Oct 2020 09:57:21

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-10-21T04:57:14', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'f7a04a86-07dc-415e-b060-af2fb4c5baad'	System	21 Oct 2020 09:57:21
User entered '21 Oct 2020 04:57:14'	System	21 Oct 2020 09:57:21

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered '21 Oct 2020 00:01'	System	07 Aug 2020 13:10:06



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered '25 Oct 2020 23:59'	System	07 Aug 2020 13:10:06

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered 'Day 92'	System	07 Aug 2020 13:10:06

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-11-04T11:08:47', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'f17108ac-53ec-40e1-8771-c17dba046a9a'	System	04 Nov 2020 17:09:37
User entered 'No (N)'	System	04 Nov 2020 17:09:37

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-11-04T11:08:54', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'f17108ac-53ec-40e1-8771-c17dba046a9a'	System	04 Nov 2020 17:09:37
User entered 'No (N)'	System	04 Nov 2020 17:09:37

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-11-04T11:08:58', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'f17108ac-53ec-40e1-8771-c17dba046a9a'	System	04 Nov 2020 17:09:37
User entered '04 Nov 2020 11:08:58'	System	04 Nov 2020 17:09:37

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered '04 Nov 2020 00:01'	System	07 Aug 2020 13:10:06

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered '08 Nov 2020 23:59'	System	07 Aug 2020 13:10:06

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered 'Day 99'	System	07 Aug 2020 13:10:06



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-11-11T01:37:41', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'f47a14ca-bdf6-4cb1-ace3-ba188d532eb7'	System	11 Nov 2020 07:37:52
User entered 'No (N)'	System	11 Nov 2020 07:37:52

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-11-11T01:37:47', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'f47a14ca-bdf6-4cb1-ace3-ba188d532eb7'	System	11 Nov 2020 07:37:52
User entered 'No (N)'	System	11 Nov 2020 07:37:52

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-11-11T01:37:51', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'f47a14ca-bdf6-4cb1-ace3-ba188d532eb7'	System	11 Nov 2020 07:37:52
User entered '11 Nov 2020 01:37:51'	System	11 Nov 2020 07:37:52

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered '11 Nov 2020 00:01'	System	07 Aug 2020 13:10:06

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered '15 Nov 2020 23:59'	System	07 Aug 2020 13:10:06

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered 'Day 106'	System	07 Aug 2020 13:10:06

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-11-18T04:19:14', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '3638f7c9-6292-4e27-9c1a-f4d5a365c21d'	System	18 Nov 2020 10:19:24
User entered 'No (N)'	System	18 Nov 2020 10:19:24

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-11-18T04:19:19', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '3638f7c9-6292-4e27-9c1a-f4d5a365c21d'	System	18 Nov 2020 10:19:24
User entered 'No (N)'	System	18 Nov 2020 10:19:24



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-11-18T04:19:23', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '3638f7c9-6292-4e27-9c1a-f4d5a365c21d' User entered '18 Nov 2020 04:19:23'	System	18 Nov 2020 10:19:24
	System	18 Nov 2020 10:19:24

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered '18 Nov 2020 00:01'	System	07 Aug 2020 13:10:06

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Feb 2021 21:25:20
Data entry locked.	System	07 Aug 2020 13:10:06
User entered '22 Nov 2020 23:59'	System	07 Aug 2020 13:10:06

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[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 (d9b5ffc77793469c)', Time: '2020-11-22T19:05:34', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '01e0ac06-5ca3-4a3e-9083-2db82d21acc3'	System	23 Nov 2020 01:05:59
User entered 'Yes (Y)'	System	23 Nov 2020 01:05:59

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Have you been exposed to someone with 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 (d9b5ffc77793469c)', Time: '2020-11-22T19:05:38', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '01e0ac06-5ca3-4a3e-9083-2db82d21acc3'	System	23 Nov 2020 01:05:59
User entered 'No (N)'	System	23 Nov 2020 01:05:59

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-11-22T19:05:42', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '01e0ac06-5ca3-4a3e-9083-2db82d21acc3'	System	23 Nov 2020 01:05:59
User entered 'No (N)'	System	23 Nov 2020 01:05:59

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-11-22T19:05:50', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '01e0ac06-5ca3-4a3e-9083-2db82d21acc3'	System	23 Nov 2020 01:05:59
User entered 'No (N)'	System	23 Nov 2020 01:05:59



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-11-22T19:05:56', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '01e0ac06-5ca3-4a3e-9083-2db82d21acc3'	System	23 Nov 2020 01:05:59
User entered '22 Nov 2020 19:05:56'	System	23 Nov 2020 01:05:59

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 15:30:12

US3002122

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:50:29

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)
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 07:56:41
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'subject was not called in error' (Site from DM).	Kimberly Mueller (b) (4)	24 Mar 2021 18:14:37
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 06:59:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-11-29T06:40:14', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '0f9c2a36-5137-4f8c-9b1f-e5bbeb1c08f1'	System	29 Nov 2020 12:40:47
User entered 'Yes (Y)'	System	29 Nov 2020 12:40:47

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Have you been exposed to someone with 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 (d9b5ffc77793469c)', Time: '2020-11-29T06:40:18', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '0f9c2a36-5137-4f8c-9b1f-e5bbeb1c08f1'	System	29 Nov 2020 12:40:47
User entered 'No (N)'	System	29 Nov 2020 12:40:47

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-11-29T06:40:22', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '0f9c2a36-5137-4f8c-9b1f-e5bbeb1c08f1'	System	29 Nov 2020 12:40:47
User entered 'No (N)'	System	29 Nov 2020 12:40:47

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-11-29T06:40:27', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '0f9c2a36-5137-4f8c-9b1f-e5bbeb1c08f1'	System	29 Nov 2020 12:40:47
User entered 'Yes (Y)'	System	29 Nov 2020 12:40:47



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-11-29T06:40:37', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '0f9c2a36-5137-4f8c-9b1f-e5bbeb1c08f1'	System	29 Nov 2020 12:40:47
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Nov 2020 12:40:47

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-11-29T06:40:40', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '0f9c2a36-5137-4f8c-9b1f-e5bbeb1c08f1'	System	29 Nov 2020 12:40:47
User entered '29 Nov 2020 06:40:40'	System	29 Nov 2020 12:40:47

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[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 (d9b5ffc77793469c)', Time: '2020-12-06T21:20:38', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '698ee20c-d1a3-4b9d-8120-77cfda18a229'	System	07 Dec 2020 03:20:48
User entered 'No (N)'	System	07 Dec 2020 03:20:48

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Have you been exposed to someone with 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 (d9b5ffc77793469c)', Time: '2020-12-06T21:20:41', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '698ee20c-d1a3-4b9d-8120-77cfda18a229'	System	07 Dec 2020 03:20:48
User entered 'No (N)'	System	07 Dec 2020 03:20:48

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-12-06T21:20:43', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '698ee20c-d1a3-4b9d-8120-77cfda18a229'	System	07 Dec 2020 03:20:48
User entered '06 Dec 2020 21:20:43'	System	07 Dec 2020 03:20:48



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[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 (d9b5ffc77793469c)', Time: '2020-12-13T08:39:05', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'f163de9f-2cb4-4562-ad15-8174651f1a22'	System	13 Dec 2020 14:39:15
User entered 'No (N)'	System	13 Dec 2020 14:39:15

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Have you been exposed to someone with 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 (d9b5ffc77793469c)', Time: '2020-12-13T08:39:08', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'f163de9f-2cb4-4562-ad15-8174651f1a22'	System	13 Dec 2020 14:39:15
User entered 'No (N)'	System	13 Dec 2020 14:39:15

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-12-13T08:39:12', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'f163de9f-2cb4-4562-ad15-8174651f1a22'	System	13 Dec 2020 14:39:15
User entered '13 Dec 2020 08:39:12'	System	13 Dec 2020 14:39:15

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 15:30:12



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[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 (d9b5ffc77793469c)', Time: '2020-12-20T19:39:59', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '701eec05-1aa5-4fb7-86ee-859ff0860037'	System	21 Dec 2020 01:40:10
User entered 'No (N)'	System	21 Dec 2020 01:40:10

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Have you been exposed to someone with 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 (d9b5ffc77793469c)', Time: '2020-12-20T19:40:02', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '701eec05-1aa5-4fb7-86ee-859ff0860037'	System	21 Dec 2020 01:40:10
User entered 'No (N)'	System	21 Dec 2020 01:40:10

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-12-20T19:40:05', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '701eec05-1aa5-4fb7-86ee-859ff0860037'	System	21 Dec 2020 01:40:10
User entered '20 Dec 2020 19:40:05'	System	21 Dec 2020 01:40:10

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[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 (d9b5ffc77793469c)', Time: '2020-12-27T08:11:12', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'd41f893f-ef0a-4b49-9f17-93d23f46ff2f'	System	27 Dec 2020 14:11:24
User entered 'No (N)'	System	27 Dec 2020 14:11:24



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Have you been exposed to someone with 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 (d9b5ffc77793469c)', Time: '2020-12-27T08:11:16', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'd41f893f-ef0a-4b49-9f17-93d23f46ff2f'	System	27 Dec 2020 14:11:24
User entered 'No (N)'	System	27 Dec 2020 14:11:24

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2020-12-27T08:11:19', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'd41f893f-ef0a-4b49-9f17-93d23f46ff2f'	System	27 Dec 2020 14:11:24
User entered '27 Dec 2020 08:11:19'	System	27 Dec 2020 14:11:24

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[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 (d9b5ffc77793469c)', Time: '2021-01-04T13:12:52', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '2f2fc7ee-1066-4acf-a7c5-6b8556c3a396'	System	04 Jan 2021 19:13:00
User entered 'No (N)'	System	04 Jan 2021 19:13:00

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Have you been exposed to someone with 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 (d9b5ffc77793469c)', Time: '2021-01-04T13:12:55', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '2f2fc7ee-1066-4acf-a7c5-6b8556c3a396'	System	04 Jan 2021 19:13:00
User entered 'No (N)'	System	04 Jan 2021 19:13:00

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2021-01-04T13:12:57', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '2f2fc7ee-1066-4acf-a7c5-6b8556c3a396'	System	04 Jan 2021 19:13:00
User entered '04 Jan 2021 13:12:57'	System	04 Jan 2021 19:13:00



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[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 (d9b5ffc77793469c)', Time: '2021-01-10T09:06:42', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '3cb72ed2-07d1-47da-9bef-324b50c44d09'	System	10 Jan 2021 15:06:47
User entered 'No (N)'	System	10 Jan 2021 15:06:47

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Have you been exposed to someone with 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 (d9b5ffc77793469c)', Time: '2021-01-10T09:06:44', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '3cb72ed2-07d1-47da-9bef-324b50c44d09'	System	10 Jan 2021 15:06:47
User entered 'No (N)'	System	10 Jan 2021 15:06:47

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2021-01-10T09:06:46', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '3cb72ed2-07d1-47da-9bef-324b50c44d09'	System	10 Jan 2021 15:06:47
User entered '10 Jan 2021 09:06:46'	System	10 Jan 2021 15:06:47

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 15:30:12



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[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 (d9b5ffc77793469c)', Time: '2021-01-17T15:32:00', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'dac3f41d-e643-4769-9b9a-cfcda32e0b41'	System	17 Jan 2021 21:32:08
User entered 'No (N)'	System	17 Jan 2021 21:32:08

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Have you been exposed to someone with 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 (d9b5ffc77793469c)', Time: '2021-01-17T15:32:03', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'dac3f41d-e643-4769-9b9a-cfcda32e0b41'	System	17 Jan 2021 21:32:08
User entered 'No (N)'	System	17 Jan 2021 21:32:08

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2021-01-17T15:32:05', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'dac3f41d-e643-4769-9b9a-cfcda32e0b41'	System	17 Jan 2021 21:32:08
User entered '17 Jan 2021 15:32:05'	System	17 Jan 2021 21:32:08

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[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 (d9b5ffc77793469c)', Time: '2021-01-24T07:34:40', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'e40d17e6-e2b2-4a7b-a8dd-862cf63791a5'	System	24 Jan 2021 13:34:48
User entered 'No (N)'	System	24 Jan 2021 13:34:48



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Have you been exposed to someone with 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 (d9b5ffc77793469c)', Time: '2021-01-24T07:34:45', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'e40d17e6-e2b2-4a7b-a8dd-862cf63791a5'	System	24 Jan 2021 13:34:48
User entered 'No (N)'	System	24 Jan 2021 13:34:48

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2021-01-24T07:34:48', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'e40d17e6-e2b2-4a7b-a8dd-862cf63791a5'	System	24 Jan 2021 13:34:48
User entered '24 Jan 2021 07:34:48'	System	24 Jan 2021 13:34:48

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[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 (d9b5ffc77793469c)', Time: '2021-01-31T06:37:48', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '73185555-6960-4a05-9ed1-92adef555e85'	System	31 Jan 2021 12:37:57
User entered 'No (N)'	System	31 Jan 2021 12:37:57

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Have you been exposed to someone with 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 (d9b5ffc77793469c)', Time: '2021-01-31T06:37:51', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '73185555-6960-4a05-9ed1-92adef555e85'	System	31 Jan 2021 12:37:57
User entered 'No (N)'	System	31 Jan 2021 12:37:57

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2021-01-31T06:37:54', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '73185555-6960-4a05-9ed1-92adef555e85' User entered '31 Jan 2021 06:37:54'	System	31 Jan 2021 12:37:57



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[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 (d9b5ffc77793469c)', Time: '2021-02-07T13:48:36', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'ccce77a7-38cc-43ef-9e60-d4aa06d985ec'	System	07 Feb 2021 19:48:43
User entered 'No (N)'	System	07 Feb 2021 19:48:43

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Have you been exposed to someone with 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 (d9b5ffc77793469c)', Time: '2021-02-07T13:48:39', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'ccce77a7-38cc-43ef-9e60-d4aa06d985ec'	System	07 Feb 2021 19:48:43
User entered 'No (N)'	System	07 Feb 2021 19:48:43

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2021-02-07T13:48:41', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'ccce77a7-38cc-43ef-9e60-d4aa06d985ec'	System	07 Feb 2021 19:48:43
User entered '07 Feb 2021 13:48:41'	System	07 Feb 2021 19:48:43

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 15:30:12



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[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 (d9b5ffc77793469c)', Time: '2021-02-14T06:24:14', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '3fefbd95-2f5b-4d09-aba6-b7819cb9b6ac'	System	14 Feb 2021 12:24:22
User entered 'No (N)'	System	14 Feb 2021 12:24:22

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Have you been exposed to someone with 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 (d9b5ffc77793469c)', Time: '2021-02-14T06:24:17', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '3fefbd95-2f5b-4d09-aba6-b7819cb9b6ac'	System	14 Feb 2021 12:24:22
User entered 'No (N)'	System	14 Feb 2021 12:24:22

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2021-02-14T06:24:19', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '3fefbd95-2f5b-4d09-aba6-b7819cb9b6ac' User entered '14 Feb 2021 06:24:19'	System	14 Feb 2021 12:24:22
	System	14 Feb 2021 12:24:22

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[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 (d9b5ffc77793469c)', Time: '2021-02-21T06:54:34', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'e2777547-ae0e-4334-8fbc-066e20a880ac'	System	21 Feb 2021 12:54:47
User entered 'No (N)'	System	21 Feb 2021 12:54:47



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Have you been exposed to someone with 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 (d9b5ffc77793469c)', Time: '2021-02-21T06:54:40', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'e2777547-ae0e-4334-8fbc-066e20a880ac'	System	21 Feb 2021 12:54:47
User entered 'No (N)'	System	21 Feb 2021 12:54:47

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2021-02-21T06:54:43', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'e2777547-ae0e-4334-8fbc-066e20a880ac' User entered '21 Feb 2021 06:54:43'	System	21 Feb 2021 12:54:47
	System	21 Feb 2021 12:54:47

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[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 (d9b5ffc77793469c)', Time: '2021-02-28T08:11:23-06:00', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'a3223cac-340b-4d7e-bdac-b6a52852bc98'	System	28 Feb 2021 14:11:33
User entered 'No (N)'	System	28 Feb 2021 14:11:33

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Have you been exposed to someone with 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 (d9b5ffc77793469c)', Time: '2021-02-28T08:11:26-06:00', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'a3223cac-340b-4d7e-bdac-b6a52852bc98'	System	28 Feb 2021 14:11:33
User entered 'No (N)'	System	28 Feb 2021 14:11:33

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2021-02-28T08:11:29-06:00', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'a3223cac-340b-4d7e-bdac-b6a52852bc98'	System	28 Feb 2021 14:11:33
User entered '28 Feb 2021 08:11:29'	System	28 Feb 2021 14:11:33



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[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 (d9b5ffc77793469c)', Time: '2021-03-07T06:16:41-06:00', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'ff691e8a-1cae-40a1-8fab-db022501f7ed'	System	07 Mar 2021 12:16:50
User entered 'No (N)'	System	07 Mar 2021 12:16:50

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Have you been exposed to someone with 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 (d9b5ffc77793469c)', Time: '2021-03-07T06:16:44-06:00', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'ff691e8a-1cae-40a1-8fab-db022501f7ed'	System	07 Mar 2021 12:16:50
User entered 'No (N)'	System	07 Mar 2021 12:16:50

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2021-03-07T06:16:49-06:00', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'ff691e8a-1cae-40a1-8fab-db022501f7ed'	System	07 Mar 2021 12:16:50
User entered '07 Mar 2021 06:16:49'	System	07 Mar 2021 12:16:50

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 15:30:12



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[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 (d9b5ffc77793469c)', Time: '2021-03-14T08:44:54-05:00', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '19b87f30-0135-4344-951e-0c98c848b59d'	System	14 Mar 2021 13:45:04
User entered 'No (N)'	System	14 Mar 2021 13:45:04

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Have you been exposed to someone with 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 (d9b5ffc77793469c)', Time: '2021-03-14T08:44:57-05:00', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '19b87f30-0135-4344-951e-0c98c848b59d'	System	14 Mar 2021 13:45:04
User entered 'No (N)'	System	14 Mar 2021 13:45:04

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2021-03-14T08:45:00-05:00', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '19b87f30-0135-4344-951e-0c98c848b59d'	System	14 Mar 2021 13:45:04
User entered '14 Mar 2021 08:45:00'	System	14 Mar 2021 13:45:04

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[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 (d9b5ffc77793469c)', Time: '2021-03-21T09:49:49-05:00', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'a2d25b91-925f-446e-a12b-75a62b619fcc'	System	21 Mar 2021 14:49:59
User entered 'No (N)'	System	21 Mar 2021 14:49:59



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Have you been exposed to someone with 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 (d9b5ffc77793469c)', Time: '2021-03-21T09:49:53-05:00', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'a2d25b91-925f-446e-a12b-75a62b619fcc'	System	21 Mar 2021 14:49:59
User entered 'No (N)'	System	21 Mar 2021 14:49:59

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2021-03-21T09:49:55-05:00', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'a2d25b91-925f-446e-a12b-75a62b619fcc'	System	21 Mar 2021 14:49:59
User entered '21 Mar 2021 09:49:55'	System	21 Mar 2021 14:49:59

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[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 (d9b5ffc77793469c)', Time: '2021-03-29T06:10:11-05:00', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '63daeeaa-7fb6-48a3-8a70-011019e3a429'	System	29 Mar 2021 11:10:17
User entered 'No (N)'	System	29 Mar 2021 11:10:17

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Have you been exposed to someone with 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 (d9b5ffc77793469c)', Time: '2021-03-29T06:10:14-05:00', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '63daeeaa-7fb6-48a3-8a70-011019e3a429'	System	29 Mar 2021 11:10:17
User entered 'No (N)'	System	29 Mar 2021 11:10:17

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2021-03-29T06:10:16-05:00', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '63daeeaa-7fb6-48a3-8a70-011019e3a429' User entered '29 Mar 2021 06:10:16'	System	29 Mar 2021 11:10:17
	System	29 Mar 2021 11:10:17



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[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 (d9b5ffc77793469c)', Time: '2021-04-11T07:41:14-05:00', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '061251c9-5e4a-468e-8b3b-ff0a5b1de6e2'	System	11 Apr 2021 12:41:22
User entered 'No (N)'	System	11 Apr 2021 12:41:22

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Have you been exposed to someone with 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 (d9b5ffc77793469c)', Time: '2021-04-11T07:41:17-05:00', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '061251c9-5e4a-468e-8b3b-ff0a5b1de6e2'	System	11 Apr 2021 12:41:22
User entered 'No (N)'	System	11 Apr 2021 12:41:22



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2021-04-11T07:41:19-05:00', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '061251c9-5e4a-468e-8b3b-ff0a5b1de6e2'	System	11 Apr 2021 12:41:22
User entered '11 Apr 2021 07:41:19'	System	11 Apr 2021 12:41:22

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[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 (d9b5ffc77793469c)', Time: '2021-04-18T14:56:04-05:00', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'a479d88a-2a74-440c-8a6f-e4df7cee4255'	System	18 Apr 2021 19:56:11
User entered 'No (N)'	System	18 Apr 2021 19:56:11

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Have you been exposed to someone with 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 (d9b5ffc77793469c)', Time: '2021-04-18T14:56:05-05:00', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'a479d88a-2a74-440c-8a6f-e4df7cee4255'	System	18 Apr 2021 19:56:11
User entered 'No (N)'	System	18 Apr 2021 19:56:11

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2021-04-18T14:56:07-05:00', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: 'a479d88a-2a74-440c-8a6f-e4df7cee4255'	System	18 Apr 2021 19:56:11
User entered '18 Apr 2021 14:56:07'	System	18 Apr 2021 19:56:11

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 15:30:12



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[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 (d9b5ffc77793469c)', Time: '2021-04-26T20:48:41-05:00', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '1bf95a0a-c5d9-454d-b382-1171f8c4f326'	System	27 Apr 2021 01:48:51
User entered 'No (N)'	System	27 Apr 2021 01:48:51

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Have you been exposed to someone with 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 (d9b5ffc77793469c)', Time: '2021-04-26T20:48:45-05:00', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '1bf95a0a-c5d9-454d-b382-1171f8c4f326'	System	27 Apr 2021 01:48:51
User entered 'No (N)'	System	27 Apr 2021 01:48:51

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2021-04-26T20:48:47-05:00', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '1bf95a0a-c5d9-454d-b382-1171f8c4f326'	System	27 Apr 2021 01:48:51
User entered '26 Apr 2021 20:48:47'	System	27 Apr 2021 01:48:51

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 15:30:12



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[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 (d9b5ffc77793469c)', Time: '2021-05-02T09:21:54-05:00', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '846b4676-f042-4795-94d7-36298d4c462d'	System	02 May 2021 14:22:02
User entered 'No (N)'	System	02 May 2021 14:22:02

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

Have you been exposed to someone with 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 (d9b5ffc77793469c)', Time: '2021-05-02T09:21:57-05:00', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '846b4676-f042-4795-94d7-36298d4c462d'	System	02 May 2021 14:22:02
User entered 'No (N)'	System	02 May 2021 14:22:02

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2021-05-02T09:21:58-05:00', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '846b4676-f042-4795-94d7-36298d4c462d'	System	02 May 2021 14:22:02
User entered '02 May 2021 09:21:58'	System	02 May 2021 14:22:02

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 15:30:12



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 15:30:12



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 15:30:12



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 15:30:12



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 15:30:12



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 15:30:12



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 15:30:12



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 15:30:12



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 15:30:12



**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 15:30:12

**US3002122**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 15:30:12



**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 15:30:12



**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 15:30:12



**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 15:30:12



**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 15:30:12



**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 15:30:12



**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 15:30:12



**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 15:30:12



**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 15:30:12



**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 15:30:12



**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 15:30:12



**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 15:30:12



**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 15:30:12



**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 15:30:12



**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 15:30:12



**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 15:30:12



**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 15:30:12



**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 15:30:12



**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 15:30:12



**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 15:30:12

**US3002122**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:50:29**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:30:12
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 15:30:12

US3002122

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 21:50:29

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:57:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2021-02-28T08:11:36-06:00', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '4d73db45-a712-42dd-9fef-f2828af49d39'	System	28 Feb 2021 14:11:43
User entered 'No (N)'	System	28 Feb 2021 14:11:43

**US3002122**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:57:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (d9b5ffc77793469c)', Time: '2021-02-28T08:11:41-06:00', User OID: 'PatientReportedOutcome (US3002122)', ODM File OID: '4d73db45-a712-42dd-9fef-f2828af49d39'	System	28 Feb 2021 14:11:43
User entered '28 Feb 2021 08:11:41'	System	28 Feb 2021 14:11:43



**US3002122**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:50:29**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 22:34:11

**US3002122**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:50:29**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '27 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 22:34:11

**US3002122**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:50:29**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 22:34:11

**US3002122**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:50:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 22:34:11

**US3002122**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:50:29**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 22:34:15

**US3002122**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:50:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:31:42
User entered 'I'	System	08 Dec 2020 22:34:15

**US3002122**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:50:29**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Yes (Y)'	(b) (4) Tiffany Nemecek (b) (4)	16 Jan 2021 05:42:35

**US3002122**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:50:29**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '03 Dec 2020'	Tiffany Nemecek (b) (4)	16 Jan 2021 05:42:35



**US3002122**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:50:29**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Contact Made (CONTACT MADE)'	Tiffany Nemecek (b) (4)	16 Jan 2021 05:42:35

**US3002122**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:50:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	Tiffany Nemecek (b) (4)	16 Jan 2021 05:42:35

**US3002122**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:50:29**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Yes (Y)'	(b) (4) Tiffany Nemecek (b) (4)	16 Jan 2021 05:42:41

**US3002122**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:50:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User entered '1'	System	16 Jan 2021 05:42:41

**US3002122**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:50:29**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Yes (Y)'	(b) (4) Tiffany Nemecek (b) (4)	16 Jan 2021 05:42:56

US3002122

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:50:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded 18FEB2021 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM). Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded 18FEB2021 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' answered with 'added' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 05:40:42
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded 18FEB2021 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	Kimberly Mueller (b) (4)	24 Mar 2021 18:15:00
User signature succeeded.	(b) (4)	
User entered '05 Jan 2021'	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
	(b) (4)	
	Tiffany Nemecek (b) (4)	16 Jan 2021 05:42:56
	(b) (4)	

**US3002122**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:50:29**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Tiffany Nemecek (b) (4)	16 Jan 2021 05:42:56

**US3002122**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:50:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	Tiffany Nemecek (b) (4)	16 Jan 2021 05:42:56



**US3002122**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:50:29**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Yes (Y)'	(b) (4) Tiffany Nemecek (b) (4)	16 Jan 2021 05:43:02

**US3002122**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:50:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User entered 'I'	System	16 Jan 2021 05:43:02

**US3002122**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:50:29**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User signature succeeded.	Brandon Essink (b) (4)	16 Mar 2021 12:43:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 18:05:00

**US3002122**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:50:29**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User signature succeeded.	Brandon Essink (b) (4)	16 Mar 2021 12:43:25
User entered '04 Feb 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 18:05:00

**US3002122**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:50:29**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User signature succeeded.	Brandon Essink (b) (4)	16 Mar 2021 12:43:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 18:05:00

**US3002122**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:50:29**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User signature succeeded.	Brandon Essink (b) (4)	16 Mar 2021 12:43:25
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 18:05:00

**US3002122**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:50:29**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User signature succeeded.	Brandon Essink (b) (4)	16 Mar 2021 12:43:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 18:05:02

**US3002122**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:50:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User entered 'I'	System	11 Mar 2021 18:05:02



**US3002122**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:50:29**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:06
User entered 'Yes (Y)'	(b) (4) Tiffany Nemecek (b) (4)	29 Mar 2021 03:07:38

**US3002122**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:50:29**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:06
User entered '18 Feb 2021'	(b) (4) Tiffany Nemecek (b) (4)	29 Mar 2021 03:07:38

**US3002122**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:50:29**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User signature succeeded.	Brandon Essink (b) (4)	29 Mar 2021 04:42:06
User entered 'Home (Home)'	Tiffany Nemecek (b) (4)	29 Mar 2021 03:07:38

**US3002122**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:50:29**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User entered 'VISIT4'	System	29 Mar 2021 03:07:38

**US3002122**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User signature succeeded.	Brandon Essink (b) (4)	01 Apr 2021 19:07:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 21:08:04

**US3002122**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User signature succeeded.	Brandon Essink (b) (4)	01 Apr 2021 19:07:28
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 21:08:04

**US3002122**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User signature succeeded.	Brandon Essink (b) (4)	01 Apr 2021 19:07:28
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 21:08:04

**US3002122**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User entered empty.	System	31 Mar 2021 21:08:04



**US3002122**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User signature succeeded.	Brandon Essink (b) (4)	01 Apr 2021 19:07:28
User entered empty.	(b) (4)	31 Mar 2021 21:08:04
	(b) (4), (b) (6)	

**US3002122**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User signature succeeded.	Brandon Essink (b) (4)	01 Apr 2021 19:07:28
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 21:08:04

**US3002122**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User signature succeeded.	Brandon Essink (b) (4)	01 Apr 2021 19:07:28
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 21:08:04

**US3002122**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User signature succeeded.	Brandon Essink (b) (4)	01 Apr 2021 19:07:28
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 21:08:04

**US3002122**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User entered empty.	System	31 Mar 2021 21:08:04

**US3002122**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User signature succeeded.	Brandon Essink (b) (4)	01 Apr 2021 19:07:28
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 21:08:04

**US3002122**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User entered empty.	System	31 Mar 2021 21:08:04

**US3002122**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User signature succeeded.	Brandon Essink (b) (4)	01 Apr 2021 19:07:28
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 21:08:04



**US3002122**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User entered empty.	System	31 Mar 2021 21:08:04

**US3002122**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User signature succeeded.	Brandon Essink (b) (4)	01 Apr 2021 19:07:28
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 21:08:04

**US3002122**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User entered empty.	System	31 Mar 2021 21:08:04

**US3002122**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08

**US3002122**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:50:29**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08

**US3002122**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:50:29**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User signature succeeded.	Brandon Essink (b) (4)	01 Apr 2021 19:07:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 21:08:20

**US3002122**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:50:29**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User signature succeeded.	Brandon Essink (b) (4)	01 Apr 2021 19:07:28
User entered '18 Feb 2021'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 21:08:20

US3002122

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:50:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User signature succeeded.	Brandon Essink (b) (4)	01 Apr 2021 19:07:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 21:08:32



**US3002122**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:50:29**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User signature succeeded.	Brandon Essink (b) (4)	01 Apr 2021 19:07:28
User entered '18 Feb 2021'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 21:08:32

**US3002122**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:50:29**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User signature succeeded.	Brandon Essink (b) (4)	01 Apr 2021 19:07:28
User entered '14:56'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 21:08:32

**US3002122**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:50:29**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User entered '18 Feb 2021 14:56'	System	31 Mar 2021 21:08:32

**US3002122**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:50:29**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User signature succeeded.	Brandon Essink (b) (4)	01 Apr 2021 19:07:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 21:08:35

**US3002122**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:50:29**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:46:08
User entered 'I'	System	31 Mar 2021 21:08:35

**US3002122**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:50:29**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:40:07
User entered 'Yes (Y)'	Kimberly Mueller (b) (4)	24 Mar 2021 18:15:27

**US3002122**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:50:29**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:40:07
User entered '18 Feb 2021'	Kimberly Mueller (b) (4)	24 Mar 2021 18:15:27

**US3002122**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:50:29**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:40:07
User entered 'Clinic (Clinic)'	Kimberly Mueller (b) (4)	24 Mar 2021 18:15:27



**US3002122**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:50:29**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User entered 'UNBLND_DECIDE'	System	24 Mar 2021 18:15:27

**US3002122**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:50:29**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:40:07
User entered '18 Feb 2021'	Kimberly Mueller (b) (4)	24 Mar 2021 18:19:22

**US3002122**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:50:29**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:40:07
User entered '0'	Kimberly Mueller (b) (4)	24 Mar 2021 18:19:22

**US3002122**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:50:29**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:40:07
User entered 'Yes (Y)'	Kimberly Mueller (b) (4)	24 Mar 2021 18:19:22

**US3002122**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:50:29**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:40:07
User entered 'Amendment 6 or later (Amendment 6 or later)'	Kimberly Mueller (b) (4)	24 Mar 2021 18:19:22

**US3002122**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:50:29**

**Date of unblinding** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:40:07
User entered '18 Feb 2021'	Kimberly Mueller (b) (4)	24 Mar 2021 18:19:22

**US3002122**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:50:29**

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:40:07
User entered 'Placebo (Placebo)'	Kimberly Mueller (b) (4)	24 Mar 2021 18:19:22

**US3002122**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:50:29**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:40:07
User entered 'Placebo (Placebo)'	Kimberly Mueller (b) (4)	24 Mar 2021 18:19:22



**US3002122**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:50:29**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:40:07
User entered 'Placebo (Placebo)'	Kimberly Mueller (b) (4)	24 Mar 2021 18:19:22

**US3002122**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:50:29**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:40:07
User entered 'No (N)'	Kimberly Mueller (b) (4)	24 Mar 2021 18:19:22

**US3002122**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:50:29**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User entered 'I'	System	24 Mar 2021 18:19:22

**US3002122**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:50:29**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User entered empty.	System	24 Mar 2021 18:19:22

**US3002122**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:50:29**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:40:07
User entered 'Yes (Y)'	Kimberly Mueller (b) (4)	24 Mar 2021 18:20:54

**US3002122**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:50:29**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:40:07
User entered '18 Feb 2021'	Kimberly Mueller (b) (4)	24 Mar 2021 18:20:54

**US3002122**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:50:29**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:40:07
User entered '14:56'	Kimberly Mueller (b) (4)	24 Mar 2021 18:20:54

**US3002122**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:50:29**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User entered '18 Feb 2021 14:56'	System	24 Mar 2021 18:20:54



**US3002122**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 21:50:29**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:40:07
User entered 'Yes (Y)'	Kimberly Mueller (b) (4)	24 Mar 2021 18:21:14

**US3002122**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 21:50:29**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:40:07
User entered '18 Feb 2021'	Kimberly Mueller (b) (4)	24 Mar 2021 18:21:14

**US3002122**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 21:50:29**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User signature succeeded.	Brandon Essink (b) (4)	25 Mar 2021 12:40:07
User entered '14:48'	Kimberly Mueller (b) (4)	24 Mar 2021 18:21:14

**US3002122**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 21:50:29**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:13:20
User entered '18 Feb 2021 14:48'	System	24 Mar 2021 18:21:14

US3002122

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 21:50:29

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 20:19:05
User closed query 'Per CDM CLR re-query: Response noted; however not been made. Kindly review and update accordingly. Otherwise clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 14:16:03
Query 'Per CDM CLR re-query: Response noted; however not been made. Kindly review and update accordingly. Otherwise clarify. Thank you.' answered with 'Patient is pregnant. Pregnancy form was completed and sent on 05DEc2020' (Site from DM).	Jessica Satorie (b) (4) (b) (4)	20 Apr 2021 13:47:29
User opened query 'Per CDM CLR re-query: Response noted; however not been made. Kindly review and update accordingly. Otherwise clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 11:24:20
User closed query 'Per CDM CLR re-query: Per new safety follow up Dairy Day 117, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 11:22:29
Query 'Per CDM CLR re-query: Per new safety follow up Dairy Day 117, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 20:53:49

US3002122

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 21:50:29

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per CDM CLR re-query: Per new safety follow up Dairy Day 117, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 07:57:13
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 17:13:22

US3002122

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
	(b) (4)	
User coded data point as SOC: Investigations, HLGT: Physical examination and organ system status topics, HLT: Physical examination procedures and organ system status, PT: Weight increased, LLT: Weight gain - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 14:07:40
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Oct 2020 14:07:40
	(b) (4)	
Data point term sent to Coder	System	02 Oct 2020 14:07:12
Coding entries removed.	(b) (4), (b) (6)	02 Oct 2020 14:06:36
	(b) (4), (b) (6)	
User entered 'weight gain' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 14:06:36
	(b) (4), (b) (6)	
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Overweight, LLT: Overweight - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:15:39
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 17:15:39
	(b) (4)	
Data point term sent to Coder	System	10 Sep 2020 17:14:47
User entered 'Overweight'	(b) (4), (b) (6)	10 Sep 2020 17:14:20
	(b) (4), (b) (6)	

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:14:20



**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:14:20

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:14:20

US3002122

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
Query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	12 Sep 2020 09:12:17
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	10 Sep 2020 17:14:20
User entered '24 Aug 2020'	(b) (4), (b) (6)	10 Sep 2020 17:14:20

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:14:20

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:50:29**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:14:20

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:14:20

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:50:29**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:14:20

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:50:29**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:14:20



**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:50:29**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:14:20

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:14:20

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:14:20

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:14:20

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:14:20

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:14:20

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:50:29**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:14:20

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:14:20



**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:14:20

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:14:20

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:14:20

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:14:20

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:14:20

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:14:20

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:14:20

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:14:20



**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:50:29**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:14:20

US3002122

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:50:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User closed query 'Per DM CLR: Other Action Taken = Medication. Please confirm if this pertains to CM #3 (PHENTERMINE). If yes, ensure that the AE term and CM indication are the same. Review and reconcile AE and CM eCRF pages as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Oct 2020 09:10:57
Query 'Per DM CLR: Other Action Taken = Medication. Please confirm if this pertains to CM #3 (PHENTERMINE). If yes, ensure that the AE term and CM indication are the same. Review and reconcile AE and CM eCRF pages as appropriate. ' answered with 'updated AE ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 14:07:10
User opened query 'Per DM CLR: Other Action Taken = Medication. Please confirm if this pertains to CM #3 (PHENTERMINE). If yes, ensure that the AE term and CM indication are the same. Review and reconcile AE and CM eCRF pages as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 07:44:29
User entered 'I'	(b) (4), (b) (6)	10 Sep 2020 17:14:20

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:14:20

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:14:20

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:50:29**

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:14:20

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 17:14:20

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Sep 2020 17:14:20

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Sep 2020 17:14:20



**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 21:50:29**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:23

US3002122

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:23
User signature succeeded.	Brandon Essink (b) (4)	16 Apr 2021 15:13:44
	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Myalgia - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 20:55:26
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 20:55:26
	(b) (4)	
Data point term sent to Coder	System	14 Apr 2021 20:54:07
User entered 'Myalgia'	(b) (4), (b) (6)	14 Apr 2021 20:53:41

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:23
User signature succeeded.	Brandon Essink (b) (4)	16 Apr 2021 15:13:44
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 20:53:41

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:23
User signature succeeded.	Brandon Essink (b) (4)	16 Apr 2021 15:13:44
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Apr 2021 20:53:41

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:23
User signature succeeded.	Brandon Essink (b) (4)	16 Apr 2021 15:13:44
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 20:53:41

US3002122

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:23
User signature succeeded.	Brandon Essink (b) (4)	16 Apr 2021 15:13:44
	(b) (4)	
User entered '29 Aug 2020'	(b) (4), (b) (6)	14 Apr 2021 20:53:41

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:23
User signature succeeded.	Brandon Essink (b) (4)	16 Apr 2021 15:13:44
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 20:53:41

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 21:50:29**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:23
User entered empty.	System	14 Apr 2021 20:53:41



**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:23
User signature succeeded.	Brandon Essink (b) (4)	16 Apr 2021 15:13:44
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 20:53:41

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 21:50:29**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:23
User signature succeeded.	Brandon Essink (b) (4)	16 Apr 2021 15:13:44
	(b) (4)	
User entered '29 Aug 2020'	(b) (4), (b) (6)	14 Apr 2021 20:53:41

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 21:50:29**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:23
User signature succeeded.	Brandon Essink (b) (4)	16 Apr 2021 15:13:44
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 20:53:41

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 21:50:29**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:23
User entered empty.	System	14 Apr 2021 20:53:41

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:23
User signature succeeded.	Brandon Essink (b) (4)	16 Apr 2021 15:13:44
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	14 Apr 2021 20:53:41

US3002122

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:23
User signature succeeded.	Brandon Essink (b) (4)	16 Apr 2021 15:13:44
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 20:53:41

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:23
User signature succeeded.	Brandon Essink (b) (4)	16 Apr 2021 15:13:44
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 20:53:41

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:23
User signature succeeded.	Brandon Essink (b) (4)	16 Apr 2021 15:13:44
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 20:53:41



**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:23
User signature succeeded.	Brandon Essink (b) (4)	16 Apr 2021 15:13:44
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 20:53:41

US3002122

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:23
User signature succeeded.	Brandon Essink (b) (4)	16 Apr 2021 15:13:44
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 20:53:41

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 21:50:29**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:23
User signature succeeded.	Brandon Essink (b) (4)	16 Apr 2021 15:13:44
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 20:53:41

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:23
User signature succeeded.	Brandon Essink (b) (4)	16 Apr 2021 15:13:44
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 20:53:41

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:23
User signature succeeded.	Brandon Essink (b) (4)	16 Apr 2021 15:13:44
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 20:53:41

US3002122

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:50:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:23
User signature succeeded.	Brandon Essink (b) (4)	16 Apr 2021 15:13:44
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 20:53:41

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:23
User signature succeeded.	Brandon Essink (b) (4)	16 Apr 2021 15:13:44
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 20:53:41

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:23
User signature succeeded.	Brandon Essink (b) (4)	16 Apr 2021 15:13:44
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 20:53:41



**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:23
User signature succeeded.	Brandon Essink (b) (4)	16 Apr 2021 15:13:44
	(b) (4)	
User entered 'Related (RELATED)'	(b) (4), (b) (6)	14 Apr 2021 20:53:41

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:23
User signature succeeded.	Brandon Essink (b) (4)	16 Apr 2021 15:13:44
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	14 Apr 2021 20:53:41

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:23
User signature succeeded.	Brandon Essink (b) (4)	16 Apr 2021 15:13:44
	(b) (4)	
User entered 'None (NONE)'	(b) (4), (b) (6)	14 Apr 2021 20:53:41

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 21:50:29**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:23
User signature succeeded.	Brandon Essink (b) (4)	16 Apr 2021 15:13:44
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 20:53:41

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:23
User signature succeeded.	Brandon Essink (b) (4)	16 Apr 2021 15:13:44
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	14 Apr 2021 20:53:41

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:23
User signature succeeded.	Brandon Essink (b) (4)	16 Apr 2021 15:13:44
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	14 Apr 2021 20:53:41

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:23
User signature succeeded.	Brandon Essink (b) (4)	16 Apr 2021 15:13:44
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	14 Apr 2021 20:53:41

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 21:50:29**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:23
User signature succeeded.	Brandon Essink (b) (4)	16 Apr 2021 15:13:44
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 20:53:41



**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:23
User signature succeeded.	Brandon Essink (b) (4)	16 Apr 2021 15:13:44
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	14 Apr 2021 20:53:41

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:23
User entered '0'	System	14 Apr 2021 20:53:41

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:23
User entered '0'	System	14 Apr 2021 20:53:41

**US3002122**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:45:23

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 11 Aug 2021 21:50:29**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:42:57
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:25:58

US3002122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:50:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: SERTRALINE HYDROCHLORIDE, PRODUCTSYNONYM: ZOLOFT - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	07 Aug 2020 15:28:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 15:28:13
Data point term sent to Coder	System	07 Aug 2020 15:27:22
User entered 'Zoloft'	(b) (4), (b) (6)	07 Aug 2020 15:26:35

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:26:35

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Depression'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:26:35



**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '50'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:26:35

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:26:35

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:50:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:26:35

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:26:35

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:50:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:26:35

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:26:35

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:50:29**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:26:35

US3002122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:50:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Aug 2020 12:01:01
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	07 Aug 2020 15:27:55
answered with 'Data correct as entered.'		
' (Site from System).		
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	07 Aug 2020 15:26:35
User entered 'un Dec 2019'	(b) (4), (b) (6)	07 Aug 2020 15:26:35



**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:26:35

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:26:35

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:50:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:26:35

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:26:35

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 15:26:35

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Aug 2020 15:26:35

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:50:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Aug 2020 15:26:35

US3002122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:50:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	11 Jan 2021 21:00:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Jan 2021 21:00:42
Data point term sent to Coder	System	11 Jan 2021 21:00:09
Coding entries removed.	(b) (4), (b) (6)	11 Jan 2021 20:59:24
User entered 'tylenol' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Jan 2021 20:59:24
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Aug 2020 15:29:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Aug 2020 15:29:18
Data point term sent to Coder	System	07 Aug 2020 15:28:23
User entered 'Acetaminophen'	(b) (4), (b) (6)	07 Aug 2020 15:27:38



**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:27:38

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Intermittent headaches'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:27:38

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '500'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:27:38

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:27:38

US3002122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:50:29

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:27:38

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:27:38

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:50:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:27:38

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:27:38



**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:50:29**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:27:38

US3002122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:50:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Oct 2020 09:06:34
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' answered with 'will update med history' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 14:02:00
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 03:12:37
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 09:21:47
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Data correct as entered.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 14:29:58
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	17 Aug 2020 14:29:55
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	17 Aug 2020 14:29:55
User entered 'un UNK 2010' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 14:29:55
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	07 Aug 2020 15:27:38

PRODUCTION RELEASE (v12.003  
EAB) (1725)

1673 of 1720

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	07 Aug 2020 15:27:38

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:27:38

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:27:38

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:50:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:27:38

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Aug 2020 15:27:38

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 15:27:38



**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 15:27:38

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:50:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Aug 2020 15:27:38

US3002122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:50:29

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:01
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: CENTRALLY ACTING ANTI OBESITY PRODUCTS, PRODUCT: PHENTERMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 21:44:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 21:44:37
Data point term sent to Coder	System	05 Jan 2021 21:43:55
Coding entries removed.	Kimberly Mueller (b) (4)	05 Jan 2021 21:43:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: CENTRALLY ACTING ANTI OBESITY PRODUCTS, PRODUCT: PHENTERMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 21:40:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 21:40:32
Data point term sent to Coder	System	05 Jan 2021 21:39:52
Coding entries removed.	Kimberly Mueller (b) (4)	05 Jan 2021 21:39:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: ANTI OBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: CENTRALLY ACTING ANTI OBESITY PRODUCTS, PRODUCT: PHENTERMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Nov 2020 01:05:25

US3002122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:50:29

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. Data point term sent to Coder Coding entries removed.	Coder Import (b) (4) (b) (4) System Tiffany Nemecek (b) (4) (b) (4)	06 Nov 2020 01:05:25  06 Nov 2020 01:04:10 06 Nov 2020 01:04:05
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: CENTRALLY ACTING ANTIOBESITY PRODUCTS, PRODUCT: PHENTERMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 14:08:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. Data point term sent to Coder Coding entries removed.	Coder Import (b) (4) (b) (4) System (b) (4), (b) (6)	02 Oct 2020 14:08:42  02 Oct 2020 14:08:12 02 Oct 2020 14:07:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: ANTIOBESITY PREPARATIONS, EXCL. DIET PRODUCTS, ATC: CENTRALLY ACTING ANTIOBESITY PRODUCTS, PRODUCT: PHENTERMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 15:54:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'Phentermine'	Coder Import (b) (4) (b) (4) System (b) (4), (b) (6)	04 Sep 2020 15:54:49  04 Sep 2020 15:54:28 04 Sep 2020 15:54:09

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:50:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:01
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 15:54:09

US3002122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:50:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:01
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User closed query 'Per DM CLR: Please note that there is no AE WEIGHT LOSS that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Jan 2021 09:22:00
User entered 'weight gain' reason for change: Data Entry Error	Kimberly Mueller (b) (4) (b) (4)	05 Jan 2021 21:43:53
Query 'Per DM CLR: Please note that there is no AE WEIGHT LOSS that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' answered with 'corrected source and EDC' (Site from DM).	Kimberly Mueller (b) (4) (b) (4)	05 Jan 2021 21:39:37
User entered 'obesity' reason for change: Data Entry Error	Kimberly Mueller (b) (4) (b) (4)	05 Jan 2021 21:39:25
User opened query 'Per DM CLR: Please note that there is no AE WEIGHT LOSS that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 16:39:25
User closed query 'Per DM CLR: Please review Indication and please update to provide the medical condition that this medication was used for, rather than the action of the medication. Please update indication as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 13:00:17
Query 'Per DM CLR: Please review Indication and please update to provide the medical condition that this medication was used for, rather than the action of the medication. Please update indication as appropriate or provide clarification. ' answered with 'Corrected' (Site from DM).	Tiffany Nemecek (b) (4) (b) (4)	06 Nov 2020 01:04:13
User entered 'WEIGHT loss' reason for change: Data Entry Error	Tiffany Nemecek (b) (4) (b) (4)	06 Nov 2020 01:04:05

US3002122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:50:29

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review Indication and please update to provide the medical condition that this medication was used for, rather than the action of the medication. Please update indication as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 18:29:05
User entered 'WEIGHT GAIN' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 14:07:40
User entered 'Weight loss'	(b) (4), (b) (6)	04 Sep 2020 15:54:09

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:50:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:01
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '37.5'	(b) (4), (b) (6)	04 Sep 2020 15:54:09



**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:50:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:01
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Sep 2020 15:54:09

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:50:29**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:01
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:54:09

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:50:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:01
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'once daily (QD)'	(b) (4), (b) (6)	04 Sep 2020 15:54:09

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:50:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:01
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:54:09

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:50:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:01
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Sep 2020 15:54:09

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:50:29**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:01
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 15:54:09

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:50:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:01
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '24 Aug 2020'	(b) (4), (b) (6)	04 Sep 2020 15:54:09

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:50:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:01
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '0'	(b) (4), (b) (6)	04 Sep 2020 15:54:09



**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:50:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:01
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	05 Jan 2021 21:47:25
User entered 'Yes (Y)'	Kimberly Mueller (b) (4)	04 Sep 2020 15:54:09
	(b) (4), (b) (6)	

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:50:29**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:01
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '21 Nov 2020' reason for change: Data Entry Error	(b) (4)	05 Jan 2021 21:47:25
User entered empty.	Kimberly Mueller (b) (4)	04 Sep 2020 15:54:09
	(b) (4), (b) (6)	

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:50:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:01
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:54:09

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:50:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:01
User entered '1'	System	04 Sep 2020 15:54:09

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:50:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:01
User entered '1'	System	04 Sep 2020 15:54:09

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:50:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:01
User entered '804 (804)'	System	04 Sep 2020 15:54:09

US3002122

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:50:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:28
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Jan 2021 21:01:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Jan 2021 21:01:42
Data point term sent to Coder	System	11 Jan 2021 21:01:11
User entered 'influenza vaccine'	(b) (4), (b) (6)	11 Jan 2021 21:00:23

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:50:29**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:28
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:00:23



**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:50:29**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:28
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'influenza prevention'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:00:23

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:50:29**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:28
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '0.5'	(b) (4), (b) (6)	11 Jan 2021 21:00:23

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:50:29**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:28
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:00:23

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:50:29**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:28
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:00:23

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:50:29**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:28
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:00:23

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:50:29**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:28
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:00:23

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:50:29**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:28
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:00:23

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:50:29**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:28
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:00:23



**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:50:29**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:28
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '24 Nov 2020'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:00:23

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:50:29**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:28
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:00:23

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:50:29**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:28
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:00:23

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:50:29**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:28
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered '24 Nov 2020'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:00:23

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:50:29**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:28
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Jan 2021 21:00:23

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:50:29**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:28
User entered empty.	System	11 Jan 2021 21:00:23

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:50:29**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:28
User entered empty.	System	11 Jan 2021 21:00:23

**US3002122**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:50:29**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:10:28
User entered empty.	System	11 Jan 2021 21:00:23



**US3002122**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 11 Aug 2021 21:50:29**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Brandon Essink (b) (4)	13 Feb 2021 13:00:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 15:52:50