

US3022021 (Prod: Meridian Clinical Research-Savannah)

Generated By: KC Joubran

Generated On: 11 Aug 2021 21:56:25

All time stamps listed in this document are displayed in GMT

US3022021

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 15:39:20

Generated On: 11 Aug 2021 21:56:25

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Participant ID

US3022021

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

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US3022021

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 15:39:31

Generated On: 11 Aug 2021 21:56:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 JUL 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

US3022021

Folder: Screening

Form: Demographics

Data signed: (b) (4) 23 Feb 2021 15:39:31

Generated On: 11 Aug 2021 21:56:25

Date of Birth (MMM yyyy)	(b) (6) 1955
Age	65
Age Units	YEARS
Age (Derived)	65
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 23 Feb 2021 15:39:31

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Date of Informed Consent (*dd MMM yyyy*) 29 JUL 2020

Month and Year of Informed Consent (derived) JUL 2020

Year of Informed Consent (derived) 2020

Protocol Version Amendment 1 ☒  
Amendment 2 ☐  
Amendment 3 ☐  
Amendment 4 ☐  
Amendment 5 ☐

Was participant enrolled in the study? Yes ☒  
No ☐

If No, indicate reason for screen fail Withdrew Consent ☐  
Inclusion/Exclusion ☐  
Cohort Full ☐  
Other ☐

If reason for screen fail is Other, specify \_\_\_\_\_  
Was this participant screened previously? Yes ☐  
No ☒

If Yes, previous participant number \_\_\_\_\_  
Enrollment Trigger 1

US3022021

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 23 Feb 2021 15:39:31

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 23 Feb 2021 15:39:31

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 25 Mar 2021 22:59:33

Generated On: 11 Aug 2021 21:56:25

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 1993
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 1993
Start Year (derived)	1993
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 25 Mar 2021 22:59:33

Generated On: 11 Aug 2021 21:56:25

Condition	BASAL CELL CARCINOMA
Start date (dd MMM yyyy)	15 JUL 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	15 JUL 2020
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JUL 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 25 Mar 2021 22:59:33

Generated On: 11 Aug 2021 21:56:25

Condition	SQUAMOUS CELL CARCINOMA
Start date (dd MMM yyyy)	15 JUL 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	15 JUL 2020
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JUL 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 25 Mar 2021 22:59:33

Generated On: 11 Aug 2021 21:56:25

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 15:39:31

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 JUL 2020
Time of assessment (00:00-23:59)	09:08 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 09:08
Height (xxx.x)	166.5 cm
Weight (xxx.x)	67.5 kg
BMI (xxx.x)	24.34867 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)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 15:39:31

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 JUL 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 23 Feb 2021 15:39:31

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Date of assessment (*dd MMM yyyy*) 29 JUL 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

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

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN UNK 1993

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 15:39:31

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☐

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**Specify**

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 15:39:31

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 15:39:31

Generated On: 11 Aug 2021 21:56:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 23 Feb 2021 15:39:31

Generated On: 11 Aug 2021 21:56:25

What was the date of randomization? (dd MMM yyyy) 29 JUL 2020

What was the participant's randomization number? 184088

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 15:39:31

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 15:39:31

Generated On: 11 Aug 2021 21:56:25

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)	29 JUL 2020
Time of assessment (00:00-23:59)	09:08 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 09:08
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)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 15:39:31

Generated On: 11 Aug 2021 21:56:25

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)	29 JUL 2020
Time of assessment (00:00-23:59)	11:03 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 11:03
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 15:39:31

Generated On: 11 Aug 2021 21:56:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 JUL 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 15:39:31

Generated On: 11 Aug 2021 21:56:25

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) 29 JUL 2020

What was the treatment time? (00:00-23:59) 10:27 (24 HR)

Treatment Date and Time (derived) 29 JUL 2020 10:27

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 15:39:31

Generated On: 11 Aug 2021 21:56:25

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 JUL 2020
Collection time (00:00-23:59)	09:38 (24 HR)
Collection date and time (derived)	29 JUL 2020 09:38

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 15:39:31

Generated On: 11 Aug 2021 21:56:25

Collection date (dd MMM yyyy)			29 JUL 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:30	29 JUL 2020 09:30
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:39:31

Generated On: 11 Aug 2021 21:56:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:56:25

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 JUL 2020 11:08

PC Open Date & Time

29 JUL 2020 10:47

PC Close Date & Time

29 JUL 2020 13:17

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:56:25

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐  
No ☒

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

PC Time Stamp	29 JUL 2020 20:14
PC Open Date & Time	29 JUL 2020 14:12
PC Close Date & Time	30 JUL 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:56:25

**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

98.7 °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

30 JUL 2020 15:18

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:56:25

**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

97.4 °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

31 JUL 2020 18:22

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3022021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:56:25

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °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

01 AUG 2020 12:29

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3022021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:56:25

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

02 AUG 2020 14:45

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3022021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:56:25

**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

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 AUG 2020 13:51

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3022021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:56:25

**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

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 12:26

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3022021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:56:25

**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

29 JUL 2020 11:09

PC Open Date & Time

29 JUL 2020 10:47

PC Close Date & Time

29 JUL 2020 13:17

US3022021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:56:25

**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

29 JUL 2020 20:14

PC Open Date & Time

29 JUL 2020 14:12

PC Close Date & Time

30 JUL 2020 11:59

US3022021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:56:25

**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

30 JUL 2020 15:19

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3022021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:56:25

**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

31 JUL 2020 18:23

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3022021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:56:25

**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

01 AUG 2020 12:30

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3022021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:56:25

**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

02 AUG 2020 14:45

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3022021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:56:25

**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

03 AUG 2020 13:51

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3022021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:56:25

**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

04 AUG 2020 12:26

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3022021

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:56:25

**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 ☐

US3022021

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:56:25

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

No ☒

Yes ☐

PC Time stamp	29 JUL 2020 11:09
PC Open Date & Time	29 JUL 2020 10:47
PC Close Date & Time	29 JUL 2020 13:17

US3022021

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:56:25

**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 ☐

US3022021

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:56:25

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

No ☒

Yes ☐

PC Time stamp	29 JUL 2020 20:15
PC Open Date & Time	29 JUL 2020 14:12
PC Close Date & Time	30 JUL 2020 11:59

US3022021

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:56:25

**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 ☒

US3022021

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:56:25

Yes <input type="checkbox"/>	
PC Time stamp	30 JUL 2020 15:20
PC Open Date & Time	30 JUL 2020 12:00
PC Close Date & Time	31 JUL 2020 11:59

US3022021

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:56:25

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3022021

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:56:25

Yes <input type="checkbox"/>	
PC Time stamp	31 JUL 2020 18:23
PC Open Date & Time	31 JUL 2020 12:00
PC Close Date & Time	01 AUG 2020 11:59

US3022021

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:56:25

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3022021

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:56:25

Yes <input type="checkbox"/>	
PC Time stamp	01 AUG 2020 12:30
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3022021

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:56:25

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 ☒

US3022021

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:56:25

Yes <input type="checkbox"/>	
PC Time stamp	02 AUG 2020 14:46
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3022021

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:56:25

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3022021

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:56:25

Yes <input type="checkbox"/>	
PC Time stamp	03 AUG 2020 13:52
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3022021

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:56:25

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 ☒

US3022021

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:56:25

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 12:26
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3022021

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:39:31

Generated On: 11 Aug 2021 21:56:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022021

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:39:31

Generated On: 11 Aug 2021 21:56:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022021

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:39:21

Generated On: 11 Aug 2021 21:56:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022021

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:39:21

Generated On: 11 Aug 2021 21:56:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022021

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:39:21

Generated On: 11 Aug 2021 21:56:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022021

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:39:21

Generated On: 11 Aug 2021 21:56:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022021

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 15:39:32

Generated On: 11 Aug 2021 21:56:25

Was this visit performed? Yes ☐  
No ☒

Visit date (dd MMM yyyy)

Was visit performed at the participant's home or at the clinic? Home ☐  
Clinic ☐

Folder OID VISIT2

US3022021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 15:39:32

Generated On: 11 Aug 2021 21:56:25

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

US3022021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 15:39:32

Generated On: 11 Aug 2021 21:56:25

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

US3022021

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 15:39:32

Generated On: 11 Aug 2021 21:56:25

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3022021

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 15:39:32

Generated On: 11 Aug 2021 21:56:25

Was study treatment given? Yes ☐  
No ☒

If No, reason not given

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

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

What was the study treatment?

What was the treatment date? (dd MMM yyyy)

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

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3022021

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 15:39:32

Generated On: 11 Aug 2021 21:56:25

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3022021

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 15:39:32

Generated On: 11 Aug 2021 21:56:25

Collection date (*dd MMM yyyy*)

Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	No		
Nasopharyngeal Swab 2	No		

US3022021

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:39:32

Generated On: 11 Aug 2021 21:56:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022021

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Apr 2021 22:10:24

Generated On: 11 Aug 2021 21:56:25

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

US3022021

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:39:21

Generated On: 11 Aug 2021 21:56:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022021

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Apr 2021 22:10:24

Generated On: 11 Aug 2021 21:56:25

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

US3022021

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:39:21

Generated On: 11 Aug 2021 21:56:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022021

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Apr 2021 22:10:24

Generated On: 11 Aug 2021 21:56:25

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

US3022021

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:39:31

Generated On: 11 Aug 2021 21:56:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022021

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 15:39:32

Generated On: 11 Aug 2021 21:56:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3022021

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 15:39:32

Generated On: 11 Aug 2021 21:56:25

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	28 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	11:21 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 11:21
Temperature ( <i>xxx.x</i> )	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	61 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	71 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3022021

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 15:39:32

Generated On: 11 Aug 2021 21:56:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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

US3022021

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 15:39:32

Generated On: 11 Aug 2021 21:56:25

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 SEP 2020
Collection time (00:00-23:59)	11:45 (24 HR)
Collection date and time (derived)	28 SEP 2020 11:45

US3022021

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:39:32

Generated On: 11 Aug 2021 21:56:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

<b>TIMEPOINT</b>	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	29 SEP 2020 14:06:30
Patient Cloud Open Date & Time	28 SEP 2020 00:01
Patient Cloud Close Date & Time	02 OCT 2020 23:59

US3022021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

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 <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"/>

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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

Date and time of submission

Patient Cloud Open Date & Time

05 OCT 2020 00:01

Patient Cloud Close Date & Time

09 OCT 2020 23:59

US3022021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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

Date and time of submission

Patient Cloud Open Date & Time

12 OCT 2020 00:01

Patient Cloud Close Date & Time

16 OCT 2020 23:59

US3022021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 OCT 2020 09:55:00
Patient Cloud Open Date & Time	26 OCT 2020 00:01
Patient Cloud Close Date & Time	30 OCT 2020 23:59

US3022021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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

Date and time of submission

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3022021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

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 <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"/>

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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

Date and time of submission

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3022021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

TIMEPOINT	DAY 113
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"/>

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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

Date and time of submission

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

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="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"/>

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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[Patient Cloud Open Date & Time](#)

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20 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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24 NOV 2020 23:59

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US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2020 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

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 <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"/>

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2020 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 DEC 2020 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 DEC 2020 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 DEC 2020 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**TIMEPOINT**

DAY 159

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

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

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2021 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

<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	12 JAN 2021 15:57:55
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

[Patient Cloud Close Date & Time](#)

19 JAN 2021 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 JAN 2021 12:10:38

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2021 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

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 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"/>

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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[Patient Cloud Open Date & Time](#)

05 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 FEB 2021 23:59

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US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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[Patient Cloud Open Date & Time](#)

12 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 FEB 2021 23:59

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US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**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

21 FEB 2021 12:01:13

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**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

02 MAR 2021 12:00:40

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**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

05 MAR 2021 07:29:18

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

<b>TIMEPOINT</b>	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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 MAR 2021 08:29:03
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

<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	19 MAR 2021 07:55:21
Patient Cloud Open Date & Time	19 MAR 2021 00:01
Patient Cloud Close Date & Time	23 MAR 2021 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 MAR 2021 08:22:35

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**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

04 APR 2021 08:01:05

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**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

12 APR 2021 13:15:05

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

<b>TIMEPOINT</b>	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	16 APR 2021 01:51:32
Patient Cloud Open Date & Time	16 APR 2021 00:01
Patient Cloud Close Date & Time	20 APR 2021 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**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

23 APR 2021 10:12:52

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**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 ☐

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

[Patient Cloud Close Date & Time](#)

04 MAY 2021 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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[Patient Cloud Open Date & Time](#)

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07 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAY 2021 23:59

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US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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[Patient Cloud Open Date & Time](#)

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14 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAY 2021 23:59

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US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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[Patient Cloud Open Date & Time](#)

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21 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAY 2021 23:59

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US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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[Patient Cloud Open Date & Time](#)

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28 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUN 2021 23:59

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US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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[Patient Cloud Open Date & Time](#)

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04 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 JUN 2021 23:59

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US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

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"/>

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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[Patient Cloud Open Date & Time](#)

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11 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 JUN 2021 23:59

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US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

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US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

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US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

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="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"/>

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

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 ☐

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**TIMEPOINT**

DAY 383

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

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US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

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

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

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

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

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US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

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="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"/>

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

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

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

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US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**TIMEPOINT**

DAY 425

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

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="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"/>

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

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US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

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="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"/>

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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[Patient Cloud Open Date & Time](#)

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15 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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19 OCT 2021 23:59

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US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

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

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

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"/>

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**TIMEPOINT**

DAY 474

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

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US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**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 ☐

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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[Patient Cloud Open Date & Time](#)

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26 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 NOV 2021 23:59

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US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**TIMEPOINT**

DAY 495

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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[Patient Cloud Open Date & Time](#)

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03 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 DEC 2021 23:59

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US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**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 ☐

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**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 ☐

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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[Patient Cloud Open Date & Time](#)

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31 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 JAN 2022 23:59

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US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

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

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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[Patient Cloud Open Date & Time](#)

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14 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 JAN 2022 23:59

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US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**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 ☐

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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[Patient Cloud Open Date & Time](#)

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21 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 JAN 2022 23:59

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US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**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 ☐

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**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 ☐

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

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US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

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 ☐

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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[Patient Cloud Open Date & Time](#)

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18 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 FEB 2022 23:59

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US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**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 ☐

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**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 ☐

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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[Patient Cloud Open Date & Time](#)

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04 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 MAR 2022 23:59

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US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

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 ☐

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

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US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

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"/>

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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[Patient Cloud Open Date & Time](#)

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18 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 MAR 2022 23:59

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US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

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 ☐

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

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US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**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 ☐ Yes ☐

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

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 ☐

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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[Patient Cloud Open Date & Time](#)

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22 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 APR 2022 23:59

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US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

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="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"/>

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

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US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

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"/>

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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[Patient Cloud Open Date & Time](#)

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27 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAY 2022 23:59

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US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

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 ☐

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

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US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

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 <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"/>

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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[Patient Cloud Open Date & Time](#)

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17 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 JUN 2022 23:59

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US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

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 ☐

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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[Patient Cloud Open Date & Time](#)

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24 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 JUN 2022 23:59

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US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**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 ☐

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 JUL 2022 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

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US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

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"/>

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

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"/>

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**TIMEPOINT**

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

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"/>

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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[Patient Cloud Open Date & Time](#)

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05 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 AUG 2022 23:59

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US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**TIMEPOINT**

DAY 747

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

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

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

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

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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[Patient Cloud Open Date & Time](#)

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26 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 AUG 2022 23:59

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US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**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 ☐

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

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US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

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US3022021

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

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

**US3022021**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

**US3022021**

**Folder: Cosmetic Injections and Dermal Fillers**

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

**Generated On: 11 Aug 2021 21:56:25**

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
<a href="#">Yes</a>	<a href="#">No</a>	<a href="#">02 MAR 2021 12:01:06</a>

US3022021

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:39:31

Generated On: 11 Aug 2021 21:56:25

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3022021

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:39:31

Generated On: 11 Aug 2021 21:56:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3022021**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Data signed:** (b) (4) 23 Feb 2021 15:39:21

**Generated On: 11 Aug 2021 21:56:25**

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 NOV 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3022021

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:39:21

Generated On: 11 Aug 2021 21:56:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022021

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 15:39:21

Generated On: 11 Aug 2021 21:56:25

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 DEC 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3022021

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:39:21

Generated On: 11 Aug 2021 21:56:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022021

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 25 Mar 2021 22:59:32

Generated On: 11 Aug 2021 21:56:25

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 \_\_\_\_\_

US3022021

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 22:59:32

Generated On: 11 Aug 2021 21:56:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3022021**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:25**

Was this visit performed? Yes ☐  
No ☐

Visit date (dd MMM yyyy) \_\_\_\_\_

Was visit performed at the participant's home or at the clinic? Home ☐  
Clinic ☐

Folder OID \_\_\_\_\_

US3022021

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:56:25

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

US3022021

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:56:25

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

**US3022021**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:56:25**

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

Collection date ( <i>dd MMM yyyy</i> )	_____
Collection time ( <i>00:00-23:59</i> )	_____
Collection date and time (derived)	_____

**US3022021**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:25**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3022021**

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

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 21:56:25**

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"/>

**US3022021**

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

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

**Generated On: 11 Aug 2021 21:56:25**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3022021

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 15:39:20

Generated On: 11 Aug 2021 21:56:25

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 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

US3022021

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

Form: Unblinding

Data signed: (b) (4) 13 Apr 2021 22:10:24

Generated On: 11 Aug 2021 21:56:25

Date of updated informed consent ( <i>dd MMM yyyy</i> )	01 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> )	01 FEB 2021
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	
Continuing with mRNA-1273	1

**US3022021**

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

**Form: Vital Signs - Dosing**

**Data signed: (b) (4) 23 Feb 2021 15:39:20**

**Generated On: 11 Aug 2021 21:56:25**

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

US3022021

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 15:39:20

Generated On: 11 Aug 2021 21:56:25

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 FEB 2021
Time of assessment (00:00-23:59)	11:22 (24 HR)
Vital Signs Date and Time (derived)	01 FEB 2021 11:22
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)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3022021

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 15:39:20

Generated On: 11 Aug 2021 21:56:25

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	01 FEB 2021
Time of assessment (00:00-23:59)	13:02 (24 HR)
Vital Signs Date and Time (derived)	01 FEB 2021 13:02
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)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3022021

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

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 15:39:20

Generated On: 11 Aug 2021 21:56:25

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 FEB 2021

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

US3022021

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

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 15:39:20

Generated On: 11 Aug 2021 21:56:25

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 01 FEB 2021

What was the treatment time? (00:00-23:59) 12:32 (24 HR)

Treatment Date and Time (derived) 01 FEB 2021 12:32

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

What was the frequency of the study treatment dosing? ONCE

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

US3022021

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 15:39:20

Generated On: 11 Aug 2021 21:56:25

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	01 FEB 2021
Collection time (00:00-23:59)	10:53 (24 HR)
Collection date and time (derived)	01 FEB 2021 10:53

US3022021

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 15:39:20

Generated On: 11 Aug 2021 21:56:25

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

Collection date (dd MMM yyyy)	01 FEB 2021
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Collection time (00:00 - 23:59)	11:01
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Collection Date and Time (derived)	01 FEB 2021 11:01
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US3022021

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

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 15:39:20

Generated On: 11 Aug 2021 21:56:25

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3022021**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:25**

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*

**US3022021**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:25**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3022021

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 15:39:20

Generated On: 11 Aug 2021 21:56:25

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

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US3022021

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Feb 2021 15:39:20

Generated On: 11 Aug 2021 21:56:25

AEID	
Adverse event	ORTHOSTATIC HYOTENSION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	14 SEP 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 type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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US3022021

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Feb 2021 15:39:20

Generated On: 11 Aug 2021 21:56:25

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input checked="" type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3022021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 15:39:20

Generated On: 11 Aug 2021 21:56:25

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

Yes ☒

No ☐

---

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

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US3022021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Feb 2021 15:39:20

Generated On: 11 Aug 2021 21:56:25

Name of Medication ESTRADOIL PATCH

Prophylaxis Yes ☐  
No ☒

Indication POST MENOPAUSAL

Dose per administration 0.0375

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

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3022021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Feb 2021 15:39:20

Generated On: 11 Aug 2021 21:56:25

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3022021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Feb 2021 15:39:20

Generated On: 11 Aug 2021 21:56:25

Name of Medication PROGESTERONE

Prophylaxis Yes ☐  
No ☒

Indication POST MENOPAUSAL

Dose per administration 90

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3022021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Feb 2021 15:39:20

Generated On: 11 Aug 2021 21:56:25

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3022021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Feb 2021 15:39:20

Generated On: 11 Aug 2021 21:56:25

Name of Medication TESTOSTERONE

Prophylaxis Yes ☐  
No ☒

Indication POST MENOPAUSAL

Dose per administration .75

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Feb 2021 15:39:20

Generated On: 11 Aug 2021 21:56:25

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3022021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Feb 2021 15:39:20

Generated On: 11 Aug 2021 21:56:25

Name of Medication TETNUS/REDUCED DIPHTHERIA  
TOXOIDS AND ACELLULAR  
PERTUSSIS VACCINE

Prophylaxis Yes ☒  
No ☐

Indication PROPHYLAXIS

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3022021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Feb 2021 15:39:20

Generated On: 11 Aug 2021 21:56:25

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input checked="" 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)		24 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3022021

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Feb 2021 15:39:20

Generated On: 11 Aug 2021 21:56:25

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3022021

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 05 Mar 2021 22:53:51

Generated On: 11 Aug 2021 21:56:25

---

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

---

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 AE#1

---

US3022021

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:56:25

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

US3022021 (Prod: Meridian Clinical Research-Savannah)

**US3022021**

**Form: Participant Creation**

**Generated On: 11 Aug 2021 21:56:25**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'US3022021'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Jul 2020 17:54:31

**US3022021**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:25**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 15:00:28

US3022021

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:56:25

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User closed query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	(b) (4) System	24 Aug 2020 21:29:48
User entered '29 Jul 2020' reason for change: Data Entry Error	Stella Yoon (b) (4)	24 Aug 2020 21:29:48
User opened query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	(b) (4) System	29 Jul 2020 15:01:24
User entered '27 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Jul 2020 17:54:32

**US3022021**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:25**

[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 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Clinic (Clinic)'	Shanice Bennett (b) (4)	29 Jul 2020 15:00:28

**US3022021**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:25**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User entered 'SCRN'	System	29 Jul 2020 15:00:28

US3022021

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:56:25

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '(b) (6)1955'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Jul 2020 17:54:33

**US3022021**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:56:25**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '65'	Shanice Bennett (b) (4)	29 Jul 2020 15:00:47

**US3022021**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:56:25**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User entered 'YEARS'	System	29 Jul 2020 15:00:47

**US3022021**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:56:25**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User entered '65'	System	29 Jul 2020 15:01:24

**US3022021**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:56:25**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Female (F)'	Shanice Bennett (b) (4)	29 Jul 2020 15:00:47

**US3022021**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:56:25**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Shanice Bennett (b) (4)	29 Jul 2020 15:00:47

**US3022021**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:56:25**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'I'	Shanice Bennett (b) (4)	29 Jul 2020 15:00:47

**US3022021**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:56:25**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 15:00:47

**US3022021**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:56:25**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 15:00:47

**US3022021**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:56:25**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 15:00:47

**US3022021**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:56:25**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 15:00:47

**US3022021**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:56:25**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 15:00:47

**US3022021**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:56:25**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 15:00:47

**US3022021**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:56:25**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 15:00:47

**US3022021**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 21:56:25**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 15:00:47

**US3022021**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:56:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '29 Jul 2020'	Shanice Bennett (b) (4)	29 Jul 2020 15:01:24

**US3022021**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:56:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User entered 'Jul 2020'	System	29 Jul 2020 15:01:24

**US3022021**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:56:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User entered '2020'	System	29 Jul 2020 15:01:24

**US3022021**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:56:25**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Amendment 1 (1)'	Shanice Bennett (b) (4)	29 Jul 2020 15:01:24

**US3022021**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:56:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 15:01:24

**US3022021**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:56:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 15:01:24

**US3022021**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:56:25**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 15:01:24

**US3022021**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:56:25**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'No (N)'	Shanice Bennett (b) (4)	29 Jul 2020 15:01:24

**US3022021**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:56:25**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	27 Jul 2020 17:54:32

**US3022021**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 21:56:25**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User entered 'I'	System	29 Jul 2020 15:01:34

**US3022021**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 11 Aug 2021 21:56:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 15:01:34

**US3022021**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 11 Aug 2021 21:56:25**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	29 Jul 2020 16:05:07
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	29 Jul 2020 15:55:30
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 15:55:18

US3022021

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:56:25

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 21:40:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 21:40:38
Data point term sent to Coder	System	29 Jul 2020 16:05:57
User entered 'POST MENOPAUSAL'	Shanice Bennett (b) (4)	29 Jul 2020 16:05:38
	(b) (4)	

**US3022021**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:56:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'UN UNK 1993'	Shanice Bennett (b) (4)	29 Jul 2020 16:05:38

**US3022021**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 16:05:38

**US3022021**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 16:05:38

**US3022021**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:56:25**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 16:05:38

**US3022021**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 16:05:38

**US3022021**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:56:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User entered 'Jan 1993'	System	29 Jul 2020 16:05:38

**US3022021**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:56:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User entered '1993'	System	29 Jul 2020 16:05:38

**US3022021**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:56:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User entered empty.	System	29 Jul 2020 16:05:38

**US3022021**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 21:56:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User entered empty.	System	29 Jul 2020 16:05:38

US3022021

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:56:25

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:33
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Basal cell carcinoma, LLT: Basal cell carcinoma - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 15:51:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 15:51:52
Data point term sent to Coder	System	24 Mar 2021 15:50:22
User entered 'Basal Cell Carcinoma'	(b) (4), (b) (6)	24 Mar 2021 15:50:05

**US3022021**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:56:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:33
User entered '15 Jul 2020'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:50:05

**US3022021**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:33
User entered '0'	(b) (4), (b) (6)	24 Mar 2021 15:50:05

**US3022021**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:50:05

**US3022021**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:56:25**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:33
User entered '15 Jul 2020'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:50:05

**US3022021**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:33
User entered '0'	(b) (4), (b) (6)	24 Mar 2021 15:50:05

**US3022021**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:56:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User entered 'Jul 2020'	System	24 Mar 2021 15:50:05

**US3022021**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:56:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User entered '2020'	System	24 Mar 2021 15:50:05

**US3022021**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:56:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User entered 'Jul 2020'	System	24 Mar 2021 15:50:05

**US3022021**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 21:56:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User entered '2020'	System	24 Mar 2021 15:50:05

US3022021

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:56:25

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:33
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLG: Miscellaneous and site unspecified neoplasms malignant and unspecified, HLT: Neoplasms malignant site unspecified NEC, PT: Squamous cell carcinoma, LLT: Squamous cell carcinoma - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 15:51:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 15:51:53
Data point term sent to Coder	System	24 Mar 2021 15:51:23
User entered 'Squamous Cell Carcinoma'	(b) (4), (b) (6)	24 Mar 2021 15:50:36

**US3022021**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 21:56:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:33
User entered '15 Jul 2020'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:50:36

**US3022021**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 21:56:25**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:33
User entered '0'	(b) (4), (b) (6)	24 Mar 2021 15:50:36

**US3022021**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 21:56:25**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:50:36

**US3022021**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 21:56:25**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:33
User entered '15 Jul 2020'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:50:36

**US3022021**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 21:56:25**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:33
User entered '0'	(b) (4), (b) (6)	24 Mar 2021 15:50:36

**US3022021**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 21:56:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User entered 'Jul 2020'	System	24 Mar 2021 15:50:36

**US3022021**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 21:56:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User entered '2020'	System	24 Mar 2021 15:50:36

**US3022021**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 21:56:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User entered 'Jul 2020'	System	24 Mar 2021 15:50:36

**US3022021**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 21:56:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User entered '2020'	System	24 Mar 2021 15:50:36

US3022021

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:56:25

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin and subcutaneous tissue therapeutic procedures NEC, PT: Dermal filler injection, LLT: Dermal filler injection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 13:24:14
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Mar 2021 13:24:14
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	25 Mar 2021 22:59:33
Data point term sent to Coder	System	24 Mar 2021 15:51:23
User entered 'Dermal fillers/Cosmetic injection'	(b) (4), (b) (6)	24 Mar 2021 15:51:21

**US3022021**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 21:56:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:33
User entered 'un UNK 2020'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:51:21

**US3022021**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 21:56:25**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:33
User entered '0'	(b) (4), (b) (6)	24 Mar 2021 15:51:21

**US3022021**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 21:56:25**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:33
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:51:21

**US3022021**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 21:56:25**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:33
User entered 'un UNK 2020'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 15:51:21

**US3022021**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 21:56:25**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:33
User entered '0'	(b) (4), (b) (6)	24 Mar 2021 15:51:21

**US3022021**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 21:56:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User entered 'Jan 2020'	System	24 Mar 2021 15:51:21

**US3022021**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 21:56:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User entered '2020'	System	24 Mar 2021 15:51:21

**US3022021**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 21:56:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User entered 'Jan 2020'	System	24 Mar 2021 15:51:21

**US3022021**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 21:56:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User entered '2020'	System	24 Mar 2021 15:51:21

**US3022021**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:25**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 15:56:08

US3022021

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:56:25

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	03 Aug 2020 18:30:09
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered with 'CORRECT, DELAYED VACCINATION ' (Site from System).	Shanice Bennett (b) (4)	29 Jul 2020 15:56:41
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	29 Jul 2020 15:56:08
User entered '29 Jul 2020'	Shanice Bennett (b) (4)	29 Jul 2020 15:56:08

**US3022021**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:25**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '09:08'	Shanice Bennett (b) (4)	29 Jul 2020 15:56:08

**US3022021**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:25**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User entered '29 Jul 2020 09:08'	System	29 Jul 2020 15:56:08

**US3022021**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:25**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '166.5' cm	(b) (4)	29 Jul 2020 15:56:08
DataPoint set to visible.	Shanice Bennett (b) (4)	29 Jul 2020 15:01:34
	(b) (4)	
	System	

**US3022021**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:25**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '67.5' kg	(b) (4) Shanice Bennett (b) (4)	29 Jul 2020 15:56:08
DataPoint set to visible.	(b) (4) System	29 Jul 2020 15:01:34

**US3022021**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:25**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
Amendment Manager: User entered '24.34867'	System	16 Sep 2020 23:36:52
User entered '24.3'	System	29 Jul 2020 15:56:08
DataPoint set to visible.	System	29 Jul 2020 15:01:34

**US3022021**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:25**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User entered 'kg/m2'	System	29 Jul 2020 15:56:08
DataPoint set to visible.	System	29 Jul 2020 15:01:34

US3022021

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:56:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded the unit should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 08:33:59
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded the unit should not remain. Please review and update as appropriate. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 18:02:22
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 18:02:14
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded the unit should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 12:28:26
User entered '36.6' C	Shanice Bennett (b) (4)	29 Jul 2020 15:56:08

**US3022021**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:25**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 18:02:14
User entered 'Oral (Oral)'	Shanice Bennett (b) (4)	29 Jul 2020 15:56:08

**US3022021**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:25**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 15:56:08

**US3022021**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:25**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 18:02:14
User entered '57'	Shanice Bennett (b) (4)	29 Jul 2020 15:56:08

**US3022021**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:25**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User entered 'bpm'	System	29 Jul 2020 15:56:08

**US3022021**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:25**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 18:02:14
User entered '15'	Shanice Bennett (b) (4)	29 Jul 2020 15:56:08

**US3022021**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:25**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User entered 'breaths/min'	System	29 Jul 2020 15:56:08

**US3022021**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:25**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 18:02:14
User entered '111'	Shanice Bennett (b) (4)	29 Jul 2020 15:56:08

**US3022021**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:25**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User entered 'mmHg'	System	29 Jul 2020 15:56:08

**US3022021**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:25**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	30 Oct 2020 18:02:14
User entered '79'	Shanice Bennett (b) (4)	29 Jul 2020 15:56:08

**US3022021**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:25**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User entered 'mmHg'	System	29 Jul 2020 15:56:08

**US3022021**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:25**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36

**US3022021**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:25**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36

**US3022021**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:56:25**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 15:56:49

**US3022021**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:56:25**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '29 Jul 2020'	Shanice Bennett (b) (4)	29 Jul 2020 15:56:49

**US3022021**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:56:25**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '29 Jul 2020'	Shanice Bennett (b) (4)	29 Jul 2020 15:57:34

**US3022021**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:56:25**

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'No (N)'	Shanice Bennett (b) (4)	29 Jul 2020 15:57:34

**US3022021**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:56:25**

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Shanice Bennett (b) (4)	29 Jul 2020 15:57:34

**US3022021**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:56:25**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 15:57:34

**US3022021**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:56:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 15:57:34

**US3022021**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:56:25**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 15:57:34

**US3022021**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:56:25**

*If Post-menopausal, date of last menstruation (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'UN UNK 1993'	Shanice Bennett (b) (4)	29 Jul 2020 15:57:34

**US3022021**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 21:56:25**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 15:57:34

US3022021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:56:25

**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 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 15:58:41

US3022021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:56:25

**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 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'No (N)'	(b) (4) Shanice Bennett (b) (4)	29 Jul 2020 15:58:41

US3022021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:56:25

**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 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'No (N)'	Shanice Bennett (b) (4)	29 Jul 2020 15:58:41

US3022021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:56:25

**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 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'No (N)'	Shanice Bennett (b) (4)	29 Jul 2020 15:58:41

US3022021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:56:25

[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 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'No (N)'	Shanice Bennett (b) (4)	29 Jul 2020 15:58:41

US3022021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:56:25

[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 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'No (N)'	Shanice Bennett (b) (4)	29 Jul 2020 15:58:41

US3022021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:56:25

**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 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'No (N)'	Shanice Bennett (b) (4)	29 Jul 2020 15:58:41

US3022021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:56:25

**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 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'No (N)'	Shanice Bennett (b) (4)	29 Jul 2020 15:58:41

US3022021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:56:25

[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 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'No (N)'	Shanice Bennett (b) (4)	29 Jul 2020 15:58:41

US3022021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:56:25

**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 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'No (N)'	Shanice Bennett (b) (4)	29 Jul 2020 15:58:41

US3022021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:56:25

**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 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'No (N)'	Shanice Bennett (b) (4)	29 Jul 2020 15:58:41

**US3022021**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 21:56:25**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'No (N)'	Shanice Bennett (b) (4)	29 Jul 2020 15:58:41

US3022021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:56:25

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 15:58:41

US3022021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:56:25

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 15:58:41

US3022021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:56:25

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 15:58:41

US3022021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:56:25

**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 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 15:58:41

US3022021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:56:25

[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 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 15:58:41

US3022021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:56:25

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 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 15:58:41

US3022021

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:56:25

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '0'	Shanice Bennett (b) (4)	29 Jul 2020 15:58:41

**US3022021**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 21:56:25**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'I'	Shanice Bennett (b) (4)	29 Jul 2020 15:58:41

**US3022021**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 21:56:25**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:06:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'ONGOING PERSON TO PERSON TRANSMISSION'	Shanice Bennett (b) (4)	29 Jul 2020 15:58:41

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:25**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 15:58:51

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '29 Jul 2020'	Shanice Bennett (b) (4)	29 Jul 2020 15:58:51

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:25**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Clinic (Clinic)'	Shanice Bennett (b) (4)	29 Jul 2020 15:58:51

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:25**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered 'VISIT1'	System	29 Jul 2020 15:58:51

US3022021

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:56:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '29 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	29 Jul 2020 13:44:33

US3022021

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:56:25

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 01:02:42
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:02:42
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Jul 2020 13:44:33
User entered '184088' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	29 Jul 2020 13:44:33

US3022021

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:56:25

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	29 Jul 2020 13:44:33

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 21:56:25**

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)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'No (N)'	Shanice Bennett (b) (4)	29 Jul 2020 15:59:14

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 21:56:25**

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)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'No (N)'	Shanice Bennett (b) (4)	29 Jul 2020 15:59:14

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 21:56:25**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'No (N)'	Shanice Bennett (b) (4)	29 Jul 2020 15:59:14

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 21:56:25**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'No (N)'	Shanice Bennett (b) (4)	29 Jul 2020 15:59:14

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 21:56:25**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'No (N)'	Shanice Bennett (b) (4)	29 Jul 2020 15:59:14

US3022021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:56:25

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 06:55:30
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 14:51:02
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 14:50:55
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 10:37:46
User entered '166.5' cm	Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:01:23

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:56:25**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	03 Nov 2020 14:50:55
User entered '67.5' kg	Morgan Deal (b) (4)	29 Jul 2020 16:01:23
	(b) (4)	

US3022021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:56:25

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 06:55:30
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 14:51:02
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 14:50:55
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 10:37:46
User entered '166.5' cm	Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:01:23

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:56:25**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	03 Nov 2020 14:50:55
User entered '67.5' kg	Morgan Deal (b) (4)	29 Jul 2020 16:01:23
	(b) (4)	

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User accepted default value 'Pre-Dose (PREDOSE)'	Shanice Bennett (b) (4)	29 Jul 2020 16:01:23
	(b) (4)	

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 16:01:23

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '29 Jul 2020'	Shanice Bennett (b) (4)	29 Jul 2020 16:01:23

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '09:08'	Shanice Bennett (b) (4)	29 Jul 2020 16:01:23

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered '29 Jul 2020 09:08'	System	29 Jul 2020 16:01:23

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '36.6' C	Shanice Bennett (b) (4)	29 Jul 2020 16:01:23

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Oral (Oral)'	Shanice Bennett (b) (4)	29 Jul 2020 16:01:23

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 16:01:23

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '57'	Shanice Bennett (b) (4)	29 Jul 2020 16:01:23

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered 'bpm'	System	29 Jul 2020 16:01:23

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '15'	Shanice Bennett (b) (4)	29 Jul 2020 16:01:23

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered 'breaths/min'	System	29 Jul 2020 16:01:23

US3022021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:56:25

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '111'	Shanice Bennett (b) (4)	29 Jul 2020 16:01:23

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered 'mmHg'	System	29 Jul 2020 16:01:23

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '79'	Shanice Bennett (b) (4)	29 Jul 2020 16:01:23

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered 'mmHg'	System	29 Jul 2020 16:01:23

US3022021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:56:25

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 06:55:30
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 14:51:02
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 14:50:55
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 10:37:46
User entered '166.5' cm	Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:01:23

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:56:25**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	03 Nov 2020 14:50:55
User entered '67.5' kg	Morgan Deal (b) (4)	29 Jul 2020 16:01:23
	(b) (4)	

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User accepted default value 'Post-Dose (POSTDOSE)'	Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:01:23

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 16:01:23

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '29 Jul 2020'	Shanice Bennett (b) (4)	29 Jul 2020 16:01:23

US3022021

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:56:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
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), (b) (6)	03 Aug 2020 18:29:42
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'CORRECT' (Site from System).	Shanice Bennett (b) (4)	29 Jul 2020 16:01:32
User opened 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).		29 Jul 2020 16:01:23
User entered '11:03'	Shanice Bennett (b) (4)	29 Jul 2020 16:01:23

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered '29 Jul 2020 11:03'	System	29 Jul 2020 16:01:23

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '36.4' C	Shanice Bennett (b) (4)	29 Jul 2020 16:01:23

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Oral (Oral)'	Shanice Bennett (b) (4)	29 Jul 2020 16:01:23

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 16:01:23

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '61'	Shanice Bennett (b) (4)	29 Jul 2020 16:01:23

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered 'bpm'	System	29 Jul 2020 16:01:23

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '16'	Shanice Bennett (b) (4)	29 Jul 2020 16:01:23

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered 'breaths/min'	System	29 Jul 2020 16:01:23

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '112'	Shanice Bennett (b) (4)	29 Jul 2020 16:01:23

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered 'mmHg'	System	29 Jul 2020 16:01:23

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '70'	Shanice Bennett (b) (4)	29 Jul 2020 16:01:23

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered 'mmHg'	System	29 Jul 2020 16:01:23

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:56:25**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 16:00:07

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:56:25**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '29 Jul 2020'	Shanice Bennett (b) (4)	29 Jul 2020 16:00:07

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:25**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 15:02:16

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:25**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 15:02:16

US3022021

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:56:25

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)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 15:02:16

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:25**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered 'MRNA-1273 OR PLACEBO'	System	29 Jul 2020 15:02:16

US3022021

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:56:25

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '29 Jul 2020'	Shanice Bennett (b) (4)	29 Jul 2020 15:02:16

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:25**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '10:27'	Shanice Bennett (b) (4)	29 Jul 2020 15:02:16

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:25**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered '29 Jul 2020 10:27'	System	29 Jul 2020 15:02:16

US3022021

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:56:25

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Left Arm (LEFT ARM)'	Shanice Bennett (b) (4)	29 Jul 2020 15:02:16

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:25**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered 'ONCE'	System	29 Jul 2020 15:02:16

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:25**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered 'INTRAMUSCULAR'	System	29 Jul 2020 15:02:16

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:56:25**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 15:59:33

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:56:25**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '29 Jul 2020'	Shanice Bennett (b) (4)	29 Jul 2020 15:59:33

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:56:25**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '09:38'	Shanice Bennett (b) (4)	29 Jul 2020 15:59:33

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:56:25**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered '29 Jul 2020 09:38'	System	29 Jul 2020 15:59:33

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 11 Aug 2021 21:56:25**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '29 Jul 2020'	Shanice Bennett (b) (4)	29 Jul 2020 15:59:51

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Shanice Bennett (b) (4)	29 Jul 2020 15:59:51

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 15:59:51

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:56:25**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '09:30'	Shanice Bennett (b) (4)	29 Jul 2020 15:59:51

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered '29 Jul 2020 09:30'	System	29 Jul 2020 15:59:51

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Shanice Bennett (b) (4)	29 Jul 2020 15:59:51

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'No (N)'	Shanice Bennett (b) (4)	29 Jul 2020 15:59:51

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	Shanice Bennett (b) (4)	29 Jul 2020 15:59:51

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered empty.	System	29 Jul 2020 15:59:51

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:25**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	29 Jul 2020 15:59:58

**US3022021**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered 'I'	System	29 Jul 2020 15:59:58

**US3022021**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
Data entry locked.	System	29 Jul 2020 15:02:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 15:02:16

US3022021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:56:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-29T11:07:58', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '74c75e9e-b94d-4922-bc85-c1c3543feb8d' User entered 'Yes (Y)'	System	29 Jul 2020 15:08:21
	System	29 Jul 2020 15:08:21

US3022021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:56:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-29T11:08:05', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '74c75e9e-b94d-4922-bc85-c1c3543feb8d' User entered '97.5'	System	29 Jul 2020 15:08:21
	System	29 Jul 2020 15:08:21

US3022021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:56:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-29T11:08:11', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '74c75e9e-b94d-4922-bc85-c1c3543feb8d' User entered 'No (N)'	System	29 Jul 2020 15:08:21
	System	29 Jul 2020 15:08:21

**US3022021**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-29T11:08:18', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '74c75e9e-b94d-4922-bc85-c1c3543feb8d' User entered '29 Jul 2020 11:08'	System	29 Jul 2020 15:08:21
	System	29 Jul 2020 15:08:21

US3022021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 21:56:25

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '29 Jul 2020 10:47'	System	29 Jul 2020 15:02:16

**US3022021**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '29 Jul 2020 13:17'	System	29 Jul 2020 15:02:16

US3022021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:56:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
Data entry locked.	System	29 Jul 2020 15:02:16
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 15:02:16

US3022021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:56:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-29T20:13:58', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '93452d95-7ce2-4c10-9baf-5be205c05858' User entered 'Yes (Y)'	System	30 Jul 2020 00:14:17
	System	30 Jul 2020 00:14:17

US3022021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:56:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-29T20:14:04', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '93452d95-7ce2-4c10-9baf-5be205c05858' User entered '97.1'	System	30 Jul 2020 00:14:17
	System	30 Jul 2020 00:14:17

US3022021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 21:56:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-29T20:14:08', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '93452d95-7ce2-4c10-9baf-5be205c05858'	System	30 Jul 2020 00:14:17
User entered 'No (N)'	System	30 Jul 2020 00:14:17

**US3022021**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-29T20:14:15', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '93452d95-7ce2-4c10-9baf-5be205c05858' User entered '29 Jul 2020 20:14'	System	30 Jul 2020 00:14:17
	System	30 Jul 2020 00:14:17

**US3022021**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '29 Jul 2020 14:12'	System	29 Jul 2020 15:02:16

**US3022021**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 15:02:16

US3022021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:56:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
Data entry locked.	System	29 Jul 2020 15:02:16
User entered 'Day 2'	System	29 Jul 2020 15:02:16

US3022021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:56:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-30T15:18:24', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '103adfdf-24d2-4553-91a4-09965bb5804c' User entered 'Yes (Y)'	System	30 Jul 2020 19:18:44
	System	30 Jul 2020 19:18:44

US3022021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:56:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-30T15:18:30', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '103adfdf-24d2-4553-91a4-09965bb5804c' User entered '98.7'	System	30 Jul 2020 19:18:44
	System	30 Jul 2020 19:18:44

US3022021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 21:56:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-30T15:18:34', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '103adfdf-24d2-4553-91a4-09965bb5804c' User entered 'No (N)'	System	30 Jul 2020 19:18:44
	System	30 Jul 2020 19:18:44

**US3022021**

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

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-30T15:18:42', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '103adfdf-24d2-4553-91a4-09965bb5804c' User entered '30 Jul 2020 15:18'	System	30 Jul 2020 19:18:44
	System	30 Jul 2020 19:18:44

**US3022021**

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

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 15:02:16

**US3022021**

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

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 15:02:16

US3022021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:56:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
Data entry locked.	System	29 Jul 2020 15:02:16
User entered 'Day 3'	System	29 Jul 2020 15:02:16

**US3022021**

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

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 21:56:25**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-31T18:22:00', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '94227c3a-7469-45c9-81bc-f0023f976489' User entered 'Yes (Y)'	System	31 Jul 2020 22:22:27
	System	31 Jul 2020 22:22:27

US3022021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:56:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-31T18:22:08', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '94227c3a-7469-45c9-81bc-f0023f976489' User entered '97.4'	System	31 Jul 2020 22:22:27
	System	31 Jul 2020 22:22:27

US3022021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 21:56:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-31T18:22:12', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '94227c3a-7469-45c9-81bc-f0023f976489' User entered 'No (N)'	System	31 Jul 2020 22:22:27
	System	31 Jul 2020 22:22:27

**US3022021**

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

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-31T18:22:26', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '94227c3a-7469-45c9-81bc-f0023f976489' User entered '31 Jul 2020 18:22'	System	31 Jul 2020 22:22:27
	System	31 Jul 2020 22:22:27

**US3022021**

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

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 15:02:16

**US3022021**

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

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 15:02:16

US3022021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:56:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
Data entry locked.	System	29 Jul 2020 15:02:16
User entered 'Day 4'	System	29 Jul 2020 15:02:16

**US3022021**

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

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 21:56:25**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-01T12:29:35', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '9d638f63-1eeb-4416-8fce-54e7ac54e45a' User entered 'Yes (Y)'	System	01 Aug 2020 16:29:50
	System	01 Aug 2020 16:29:50

US3022021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:56:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-01T12:29:41', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '9d638f63-1eeb-4416-8fce-54e7ac54e45a' User entered '96.8'	System	01 Aug 2020 16:29:50
	System	01 Aug 2020 16:29:50

US3022021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 21:56:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-01T12:29:44', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '9d638f63-1eeb-4416-8fce-54e7ac54e45a'	System	01 Aug 2020 16:29:50
User entered 'No (N)'	System	01 Aug 2020 16:29:50

**US3022021**

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

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-01T12:29:49', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '9d638f63-1eeb-4416-8fce-54e7ac54e45a'	System	01 Aug 2020 16:29:50
User entered '01 Aug 2020 12:29'	System	01 Aug 2020 16:29:50

**US3022021**

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

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 15:02:16

**US3022021**

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

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 15:02:16

US3022021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:56:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
Data entry locked.	System	29 Jul 2020 15:02:16
User entered 'Day 5'	System	29 Jul 2020 15:02:16

**US3022021**

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

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

**Generated On: 11 Aug 2021 21:56:25**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-02T14:45:06', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '8ef8bcb0-0342-4fb9-a921-e0c3ec6c291e' User entered 'Yes (Y)'	System	02 Aug 2020 18:45:36
	System	02 Aug 2020 18:45:36

US3022021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:56:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-02T14:45:23', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '8ef8bcb0-0342-4fb9-a921-e0c3ec6c291e' User entered '97.0'	System	02 Aug 2020 18:45:36
	System	02 Aug 2020 18:45:36

US3022021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 21:56:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-02T14:45:27', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '8ef8bcb0-0342-4fb9-a921-e0c3ec6c291e'	System	02 Aug 2020 18:45:36
User entered 'No (N)'	System	02 Aug 2020 18:45:36

**US3022021**

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

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

**Generated On: 11 Aug 2021 21:56:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-02T14:45:31', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '8ef8bcb0-0342-4fb9-a921-e0c3ec6c291e' User entered '02 Aug 2020 14:45'	System	02 Aug 2020 18:45:36
	System	02 Aug 2020 18:45:36

**US3022021**

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

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

**Generated On: 11 Aug 2021 21:56:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 15:02:16

**US3022021**

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

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

**Generated On: 11 Aug 2021 21:56:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 15:02:16

US3022021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:56:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
Data entry locked.	System	29 Jul 2020 15:02:16
User entered 'Day 6'	System	29 Jul 2020 15:02:16

US3022021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:56:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-03T13:51:13', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '703bc464-2ac1-48b1-a9a8-162c8a33cf28'	System	03 Aug 2020 17:51:30
User entered 'Yes (Y)'	System	03 Aug 2020 17:51:30

US3022021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:56:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-03T13:51:19', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '703bc464-2ac1-48b1-a9a8-162c8a33cf28' User entered '96.5'	System	03 Aug 2020 17:51:30
	System	03 Aug 2020 17:51:30

US3022021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 21:56:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-03T13:51:22', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '703bc464-2ac1-48b1-a9a8-162c8a33cf28'	System	03 Aug 2020 17:51:30
User entered 'No (N)'	System	03 Aug 2020 17:51:30

**US3022021**

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

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

**Generated On: 11 Aug 2021 21:56:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-03T13:51:26', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '703bc464-2ac1-48b1-a9a8-162c8a33cf28' User entered '03 Aug 2020 13:51'	System	03 Aug 2020 17:51:30
	System	03 Aug 2020 17:51:30

**US3022021**

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

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

**Generated On: 11 Aug 2021 21:56:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 15:02:16

**US3022021**

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

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

**Generated On: 11 Aug 2021 21:56:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 15:02:16

US3022021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:56:25

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
Data entry locked.	System	29 Jul 2020 15:02:16
User entered 'Day 7'	System	29 Jul 2020 15:02:16

US3022021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:56:25

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-04T12:26:08', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '8ced15e4-f328-4016-a764-18431b938987' User entered 'Yes (Y)'	System	04 Aug 2020 16:26:24
	System	04 Aug 2020 16:26:24

US3022021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:56:25

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-04T12:26:13', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '8ced15e4-f328-4016-a764-18431b938987' User entered '96.7'	System	04 Aug 2020 16:26:24
	System	04 Aug 2020 16:26:24

US3022021

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 21:56:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-04T12:26:16', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '8ced15e4-f328-4016-a764-18431b938987' User entered 'No (N)'	System	04 Aug 2020 16:26:24
	System	04 Aug 2020 16:26:24

**US3022021**

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

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

**Generated On: 11 Aug 2021 21:56:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-04T12:26:19', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '8ced15e4-f328-4016-a764-18431b938987' User entered '04 Aug 2020 12:26'	System	04 Aug 2020 16:26:24
	System	04 Aug 2020 16:26:24

**US3022021**

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

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

**Generated On: 11 Aug 2021 21:56:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '04 Aug 2020 12:00'	System	29 Jul 2020 15:02:16

**US3022021**

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

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

**Generated On: 11 Aug 2021 21:56:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '05 Aug 2020 11:59'	System	29 Jul 2020 15:02:16

**US3022021**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
Data entry locked.	System	29 Jul 2020 15:02:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 15:02:16

US3022021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:56:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-29T11:08:36', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '75fd46ad-7ebe-4fe8-8e8c-aef09b0e356e'	System	29 Jul 2020 15:09:13
User entered 'None (1)'	System	29 Jul 2020 15:09:13

US3022021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:56:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-29T11:08:48', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '75fd46ad-7ebe-4fe8-8e8c-aef09b0e356e' User entered 'No (N)'	System	29 Jul 2020 15:09:13
	System	29 Jul 2020 15:09:13

US3022021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:56:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-29T11:08:52', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '75fd46ad-7ebe-4fe8-8e8c-aef09b0e356e' User entered 'No (N)'	System	29 Jul 2020 15:09:13
	System	29 Jul 2020 15:09:13

US3022021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 21:56:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-29T11:08:57', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '75fd46ad-7ebe-4fe8-8e8c-aef09b0e356e'	System	29 Jul 2020 15:09:13
User entered 'None (1)'	System	29 Jul 2020 15:09:13

**US3022021**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-29T11:09:02', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '75fd46ad-7ebe-4fe8-8e8c-aef09b0e356e'	System	29 Jul 2020 15:09:13
User entered '29 Jul 2020 11:09'	System	29 Jul 2020 15:09:13

**US3022021**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '29 Jul 2020 10:47'	System	29 Jul 2020 15:02:16

**US3022021**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '29 Jul 2020 13:17'	System	29 Jul 2020 15:02:16

**US3022021**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
Data entry locked.	System	29 Jul 2020 15:02:16
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 15:02:16

US3022021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:56:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-29T20:14:22', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '8701e66a-2f16-4569-941e-db9ef9a39270'	System	30 Jul 2020 00:15:03
User entered 'None (1)'	System	30 Jul 2020 00:15:03

US3022021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:56:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-29T20:14:42', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '8701e66a-2f16-4569-941e-db9ef9a39270'	System	30 Jul 2020 00:15:03
User entered 'No (N)'	System	30 Jul 2020 00:15:03

US3022021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:56:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-29T20:14:48', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '8701e66a-2f16-4569-941e-db9ef9a39270'	System	30 Jul 2020 00:15:03
User entered 'No (N)'	System	30 Jul 2020 00:15:03

US3022021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 21:56:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-29T20:14:55', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '8701e66a-2f16-4569-941e-db9ef9a39270'	System	30 Jul 2020 00:15:03
User entered 'None (1)'	System	30 Jul 2020 00:15:03

**US3022021**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-29T20:14:59', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '8701e66a-2f16-4569-941e-db9ef9a39270' User entered '29 Jul 2020 20:14'	System	30 Jul 2020 00:15:03
	System	30 Jul 2020 00:15:03

**US3022021**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '29 Jul 2020 14:12'	System	29 Jul 2020 15:02:16

**US3022021**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 15:02:16

**US3022021**

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

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
Data entry locked.	System	29 Jul 2020 15:02:16
User entered 'Day 2'	System	29 Jul 2020 15:02:16

US3022021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:56:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-30T15:19:13', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '9d3bf0ce-1a19-454e-aeb1-3e14ade7bb53'	System	30 Jul 2020 19:19:51
User entered 'Does not interfere with activity (2)'	System	30 Jul 2020 19:19:51

US3022021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:56:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-30T15:19:17', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '9d3bf0ce-1a19-454e-aeb1-3e14ade7bb53'	System	30 Jul 2020 19:19:51
User entered 'No (N)'	System	30 Jul 2020 19:19:51

US3022021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:56:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-30T15:19:26', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '9d3bf0ce-1a19-454e-aeb1-3e14ade7bb53'	System	30 Jul 2020 19:19:51
User entered 'No (N)'	System	30 Jul 2020 19:19:51

US3022021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 21:56:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-30T15:19:37', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '9d3bf0ce-1a19-454e-aeb1-3e14ade7bb53'	System	30 Jul 2020 19:19:51
User entered 'None (1)'	System	30 Jul 2020 19:19:51

**US3022021**

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

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-30T15:19:46', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '9d3bf0ce-1a19-454e-aeb1-3e14ade7bb53' User entered '30 Jul 2020 15:19'	System	30 Jul 2020 19:19:51
	System	30 Jul 2020 19:19:51

**US3022021**

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

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 15:02:16

**US3022021**

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

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 15:02:16

**US3022021**

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

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
Data entry locked.	System	29 Jul 2020 15:02:16
User entered 'Day 3'	System	29 Jul 2020 15:02:16

US3022021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:56:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-31T18:22:33', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '1d97ed1c-6b8a-46d6-8fab-05ea81fe7925'	System	31 Jul 2020 22:23:07
User entered 'Does not interfere with activity (2)'	System	31 Jul 2020 22:23:07

US3022021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:56:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-31T18:22:44', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '1d97ed1c-6b8a-46d6-8fab-05ea81fe7925'	System	31 Jul 2020 22:23:07
User entered 'No (N)'	System	31 Jul 2020 22:23:07

US3022021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:56:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-31T18:22:54', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '1d97ed1c-6b8a-46d6-8fab-05ea81fe7925' User entered 'No (N)'	System	31 Jul 2020 22:23:07
	System	31 Jul 2020 22:23:07

US3022021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 21:56:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-31T18:22:58', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '1d97ed1c-6b8a-46d6-8fab-05ea81fe7925'	System	31 Jul 2020 22:23:07
User entered 'None (1)'	System	31 Jul 2020 22:23:07

**US3022021**

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

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-31T18:23:05', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '1d97ed1c-6b8a-46d6-8fab-05ea81fe7925'	System	31 Jul 2020 22:23:07
User entered '31 Jul 2020 18:23'	System	31 Jul 2020 22:23:07

**US3022021**

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

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 15:02:16

**US3022021**

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

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 15:02:16

**US3022021**

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

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
Data entry locked.	System	29 Jul 2020 15:02:16
User entered 'Day 4'	System	29 Jul 2020 15:02:16

US3022021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:56:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-01T12:29:57', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: 'fec92592-19d4-4492-a17d-c009a0075c55'	System	01 Aug 2020 16:30:09
User entered 'Does not interfere with activity (2)'	System	01 Aug 2020 16:30:09

US3022021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:56:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-01T12:30:00', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: 'fec92592-19d4-4492-a17d-c009a0075c55'	System	01 Aug 2020 16:30:09
User entered 'No (N)'	System	01 Aug 2020 16:30:09

US3022021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:56:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-01T12:30:02', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: 'fec92592-19d4-4492-a17d-c009a0075c55'	System	01 Aug 2020 16:30:09
User entered 'No (N)'	System	01 Aug 2020 16:30:09

US3022021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 21:56:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-01T12:30:04', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: 'fec92592-19d4-4492-a17d-c009a0075c55'	System	01 Aug 2020 16:30:09
User entered 'None (1)'	System	01 Aug 2020 16:30:09

**US3022021**

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

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-01T12:30:07', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: 'fec92592-19d4-4492-a17d-c009a0075c55'	System	01 Aug 2020 16:30:09
User entered '01 Aug 2020 12:30'	System	01 Aug 2020 16:30:09

**US3022021**

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

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 15:02:16

**US3022021**

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

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 15:02:16

**US3022021**

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

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
Data entry locked.	System	29 Jul 2020 15:02:16
User entered 'Day 5'	System	29 Jul 2020 15:02:16

US3022021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:56:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-02T14:45:36', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: 'e7434eb1-f1e7-4e7e-8507-7298aea8ceal'	System	02 Aug 2020 18:45:53
User entered 'None (1)'	System	02 Aug 2020 18:45:53

US3022021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:56:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-02T14:45:39', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: 'e7434eb1-f1e7-4e7e-8507-7298aea8ceal'	System	02 Aug 2020 18:45:53
User entered 'No (N)'	System	02 Aug 2020 18:45:53

US3022021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:56:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-02T14:45:41', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: 'e7434eb1-f1e7-4e7e-8507-7298aea8ceal'	System	02 Aug 2020 18:45:53
User entered 'No (N)'	System	02 Aug 2020 18:45:53

US3022021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 21:56:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-02T14:45:43', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: 'e7434eb1-f1e7-4e7e-8507-7298aea8ceal'	System	02 Aug 2020 18:45:53
User entered 'None (1)'	System	02 Aug 2020 18:45:53

**US3022021**

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

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-02T14:45:49', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: 'e7434eb1-f1e7-4e7e-8507-7298aea8ceal' User entered '02 Aug 2020 14:45'	System	02 Aug 2020 18:45:53
	System	02 Aug 2020 18:45:53

**US3022021**

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

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 15:02:16

**US3022021**

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

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 15:02:16

**US3022021**

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

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
Data entry locked.	System	29 Jul 2020 15:02:16
User entered 'Day 6'	System	29 Jul 2020 15:02:16

US3022021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:56:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-03T13:51:30', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '55fec870-d3c1-418d-b6e3-716bb073e574'	System	03 Aug 2020 17:51:44
User entered 'None (1)'	System	03 Aug 2020 17:51:44

US3022021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:56:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-03T13:51:34', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '55fec870-d3c1-418d-b6e3-716bb073e574' User entered 'No (N)'	System	03 Aug 2020 17:51:44
	System	03 Aug 2020 17:51:44

US3022021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:56:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-03T13:51:37', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '55fec870-d3c1-418d-b6e3-716bb073e574' User entered 'No (N)'	System	03 Aug 2020 17:51:44
	System	03 Aug 2020 17:51:44

US3022021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 21:56:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-03T13:51:39', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '55fec870-d3c1-418d-b6e3-716bb073e574'	System	03 Aug 2020 17:51:44
User entered 'None (1)'	System	03 Aug 2020 17:51:44

**US3022021**

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

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-03T13:51:42', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '55fec870-d3c1-418d-b6e3-716bb073e574' User entered '03 Aug 2020 13:51'	System	03 Aug 2020 17:51:44
	System	03 Aug 2020 17:51:44

**US3022021**

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

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 15:02:16

**US3022021**

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

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 15:02:16

**US3022021**

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

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
Data entry locked.	System	29 Jul 2020 15:02:16
User entered 'Day 7'	System	29 Jul 2020 15:02:16

US3022021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:56:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-04T12:26:24', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '43e2906c-9809-4f4c-91a0-8a339598ce9f' User entered 'None (1)'	System	04 Aug 2020 16:26:36
	System	04 Aug 2020 16:26:36

US3022021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:56:25

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-04T12:26:26', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '43e2906c-9809-4f4c-91a0-8a339598ce9f' User entered 'No (N)'	System	04 Aug 2020 16:26:36
	System	04 Aug 2020 16:26:36

US3022021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:56:25

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-04T12:26:28', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '43e2906c-9809-4f4c-91a0-8a339598ce9f' User entered 'No (N)'	System	04 Aug 2020 16:26:36
	System	04 Aug 2020 16:26:36

US3022021

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 21:56:25

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-04T12:26:30', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '43e2906c-9809-4f4c-91a0-8a339598ce9f' User entered 'None (1)'	System	04 Aug 2020 16:26:36
	System	04 Aug 2020 16:26:36

**US3022021**

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

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-04T12:26:33', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '43e2906c-9809-4f4c-91a0-8a339598ce9f' User entered '04 Aug 2020 12:26'	System	04 Aug 2020 16:26:36
	System	04 Aug 2020 16:26:36

**US3022021**

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

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '04 Aug 2020 12:00'	System	29 Jul 2020 15:02:16

**US3022021**

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

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '05 Aug 2020 11:59'	System	29 Jul 2020 15:02:16

**US3022021**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
Data entry locked.	System	29 Jul 2020 15:02:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 15:02:16

**US3022021**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:56:25**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-29T11:09:08', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '18c7c6b0-5a13-4470-933a-0dbf54e72e97'	System	29 Jul 2020 15:09:45
User entered 'None (0)'	System	29 Jul 2020 15:09:45

**US3022021**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:56:25**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-29T11:09:11', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '18c7c6b0-5a13-4470-933a-0dbf54e72e97' User entered 'None (0)'	System	29 Jul 2020 15:09:45
	System	29 Jul 2020 15:09:45

US3022021

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:56:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-29T11:09:15', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '18c7c6b0-5a13-4470-933a-0dbf54e72e97' User entered 'None (0)'	System	29 Jul 2020 15:09:45
	System	29 Jul 2020 15:09:45

US3022021

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:56:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-29T11:09:17', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '18c7c6b0-5a13-4470-933a-0dbf54e72e97' User entered 'None (0)'	System	29 Jul 2020 15:09:45
	System	29 Jul 2020 15:09:45

**US3022021**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:56:25**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-29T11:09:20', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '18c7c6b0-5a13-4470-933a-0dbf54e72e97' User entered 'None (0)'	System	29 Jul 2020 15:09:45
	System	29 Jul 2020 15:09:45

**US3022021**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:56:25**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-29T11:09:23', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '18c7c6b0-5a13-4470-933a-0dbf54e72e97'	System	29 Jul 2020 15:09:45
User entered 'None (0)'	System	29 Jul 2020 15:09:45

US3022021

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 21:56:25

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)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-29T11:09:30', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '18c7c6b0-5a13-4470-933a-0dbf54e72e97' User entered 'No (N)'	System	29 Jul 2020 15:09:45
	System	29 Jul 2020 15:09:45

**US3022021**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-29T11:09:33', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '18c7c6b0-5a13-4470-933a-0dbf54e72e97'	System	29 Jul 2020 15:09:45
User entered '29 Jul 2020 11:09'	System	29 Jul 2020 15:09:45

**US3022021**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '29 Jul 2020 10:47'	System	29 Jul 2020 15:02:16

**US3022021**

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

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '29 Jul 2020 13:17'	System	29 Jul 2020 15:02:16

**US3022021**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
Data entry locked.	System	29 Jul 2020 15:02:16
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 15:02:16

**US3022021**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:56:25**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-29T20:15:08', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: 'ab78b8b3-f614-4067-b3be-1b7636318232' User entered 'None (0)'	System	30 Jul 2020 00:15:44
	System	30 Jul 2020 00:15:44

**US3022021**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:56:25**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-29T20:15:12', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: 'ab78b8b3-f614-4067-b3be-1b7636318232' User entered 'None (0)'	System	30 Jul 2020 00:15:44
	System	30 Jul 2020 00:15:44

US3022021

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:56:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-29T20:15:15', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: 'ab78b8b3-f614-4067-b3be-1b7636318232' User entered 'None (0)'	System	30 Jul 2020 00:15:44
	System	30 Jul 2020 00:15:44

**US3022021**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:56:25**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-29T20:15:18', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: 'ab78b8b3-f614-4067-b3be-1b7636318232' User entered 'None (0)'	System	30 Jul 2020 00:15:44
	System	30 Jul 2020 00:15:44

**US3022021**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:56:25**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-29T20:15:21', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: 'ab78b8b3-f614-4067-b3be-1b7636318232' User entered 'None (0)'	System	30 Jul 2020 00:15:44
	System	30 Jul 2020 00:15:44

**US3022021**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:56:25**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-29T20:15:25', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: 'ab78b8b3-f614-4067-b3be-1b7636318232' User entered 'None (0)'	System	30 Jul 2020 00:15:44
	System	30 Jul 2020 00:15:44

US3022021

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 21:56:25

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)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-29T20:15:28', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: 'ab78b8b3-f614-4067-b3be-1b7636318232' User entered 'No (N)'	System	30 Jul 2020 00:15:44
	System	30 Jul 2020 00:15:44

**US3022021**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-29T20:15:39', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: 'ab78b8b3-f614-4067-b3be-1b7636318232' User entered '29 Jul 2020 20:15'	System	30 Jul 2020 00:15:44
	System	30 Jul 2020 00:15:44

**US3022021**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '29 Jul 2020 14:12'	System	29 Jul 2020 15:02:16

**US3022021**

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

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 15:02:16

**US3022021**

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

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
Data entry locked.	System	29 Jul 2020 15:02:16
User entered 'Day 2'	System	29 Jul 2020 15:02:16

**US3022021**

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

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:56:25**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-30T15:20:00', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '0d53ca88-672c-41f2-8268-dadc74b33f8e'	System	30 Jul 2020 19:20:45
User entered 'No interference with activity (1)'	System	30 Jul 2020 19:20:45

**US3022021**

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

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:56:25**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-30T15:20:05', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '0d53ca88-672c-41f2-8268-dadc74b33f8e' User entered 'None (0)'	System	30 Jul 2020 19:20:45
	System	30 Jul 2020 19:20:45

US3022021

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:56:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-30T15:20:13', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '0d53ca88-672c-41f2-8268-dadc74b33f8e' User entered 'None (0)'	System	30 Jul 2020 19:20:45
	System	30 Jul 2020 19:20:45

US3022021

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:56:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-30T15:20:16', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '0d53ca88-672c-41f2-8268-dadc74b33f8e' User entered 'None (0)'	System	30 Jul 2020 19:20:45
	System	30 Jul 2020 19:20:45

**US3022021**

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

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:56:25**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-30T15:20:20', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '0d53ca88-672c-41f2-8268-dadc74b33f8e' User entered 'None (0)'	System	30 Jul 2020 19:20:45
	System	30 Jul 2020 19:20:45

**US3022021**

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

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:56:25**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-30T15:20:23', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '0d53ca88-672c-41f2-8268-dadc74b33f8e' User entered 'None (0)'	System	30 Jul 2020 19:20:45
	System	30 Jul 2020 19:20:45

US3022021

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 21:56:25

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)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-30T15:20:33', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '0d53ca88-672c-41f2-8268-dadc74b33f8e' User entered 'No (N)'	System	30 Jul 2020 19:20:45
	System	30 Jul 2020 19:20:45

**US3022021**

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

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-30T15:20:43', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '0d53ca88-672c-41f2-8268-dadc74b33f8e' User entered '30 Jul 2020 15:20'	System	30 Jul 2020 19:20:45
	System	30 Jul 2020 19:20:45

**US3022021**

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

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 15:02:16

**US3022021**

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

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 15:02:16

**US3022021**

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

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
Data entry locked.	System	29 Jul 2020 15:02:16
User entered 'Day 3'	System	29 Jul 2020 15:02:16

**US3022021**

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

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:56:25**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-31T18:23:21', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '26767490-d40e-4c05-aced-69f16abe2441' User entered 'None (0)'	System	31 Jul 2020 22:23:53
	System	31 Jul 2020 22:23:53

**US3022021**

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

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:56:25**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-31T18:23:24', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '26767490-d40e-4c05-aced-69f16abe2441' User entered 'None (0)'	System	31 Jul 2020 22:23:53
	System	31 Jul 2020 22:23:53

**US3022021**

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

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:56:25**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-31T18:23:27', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '26767490-d40e-4c05-aced-69f16abe2441' User entered 'None (0)'	System	31 Jul 2020 22:23:53
	System	31 Jul 2020 22:23:53

US3022021

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:56:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-31T18:23:30', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '26767490-d40e-4c05-aced-69f16abe2441' User entered 'None (0)'	System	31 Jul 2020 22:23:53
	System	31 Jul 2020 22:23:53

**US3022021**

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

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:56:25**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-31T18:23:32', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '26767490-d40e-4c05-aced-69f16abe2441' User entered 'None (0)'	System	31 Jul 2020 22:23:53
	System	31 Jul 2020 22:23:53

**US3022021**

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

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:56:25**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-31T18:23:36', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '26767490-d40e-4c05-aced-69f16abe2441' User entered 'None (0)'	System	31 Jul 2020 22:23:53
	System	31 Jul 2020 22:23:53

US3022021

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 21:56:25

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)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-31T18:23:39', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '26767490-d40e-4c05-aced-69f16abe2441' User entered 'No (N)'	System	31 Jul 2020 22:23:53
	System	31 Jul 2020 22:23:53

**US3022021**

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

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-07-31T18:23:50', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '26767490-d40e-4c05-aced-69f16abe2441' User entered '31 Jul 2020 18:23'	System	31 Jul 2020 22:23:53
	System	31 Jul 2020 22:23:53

**US3022021**

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

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 15:02:16

**US3022021**

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

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 15:02:16

**US3022021**

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

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
Data entry locked.	System	29 Jul 2020 15:02:16
User entered 'Day 4'	System	29 Jul 2020 15:02:16

**US3022021**

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

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:56:25**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-01T12:30:12', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '0c4edfc6-7050-412f-8c9b-2d104f2c57bf' User entered 'None (0)'	System	01 Aug 2020 16:30:32
	System	01 Aug 2020 16:30:32

**US3022021**

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

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:56:25**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-01T12:30:14', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '0c4edfc6-7050-412f-8c9b-2d104f2c57bf' User entered 'None (0)'	System	01 Aug 2020 16:30:32
	System	01 Aug 2020 16:30:32

US3022021

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:56:25

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-01T12:30:17', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '0c4edfc6-7050-412f-8c9b-2d104f2c57bf' User entered 'None (0)'	System	01 Aug 2020 16:30:32
	System	01 Aug 2020 16:30:32

US3022021

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:56:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-01T12:30:20', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '0c4edfc6-7050-412f-8c9b-2d104f2c57bf' User entered 'None (0)'	System	01 Aug 2020 16:30:32
	System	01 Aug 2020 16:30:32

**US3022021**

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

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:56:25**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-01T12:30:22', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '0c4edfc6-7050-412f-8c9b-2d104f2c57bf' User entered 'None (0)'	System	01 Aug 2020 16:30:32
	System	01 Aug 2020 16:30:32

**US3022021**

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

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:56:25**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-01T12:30:24', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '0c4edfc6-7050-412f-8c9b-2d104f2c57bf' User entered 'None (0)'	System	01 Aug 2020 16:30:32
	System	01 Aug 2020 16:30:32

US3022021

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 21:56:25

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)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-01T12:30:28', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '0c4edfc6-7050-412f-8c9b-2d104f2c57bf' User entered 'No (N)'	System	01 Aug 2020 16:30:32
	System	01 Aug 2020 16:30:32

**US3022021**

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

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-01T12:30:31', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '0c4edfc6-7050-412f-8c9b-2d104f2c57bf' User entered '01 Aug 2020 12:30'	System	01 Aug 2020 16:30:32
	System	01 Aug 2020 16:30:32

**US3022021**

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

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 15:02:16

**US3022021**

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

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 15:02:16

**US3022021**

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

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

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
Data entry locked.	System	29 Jul 2020 15:02:16
User entered 'Day 5'	System	29 Jul 2020 15:02:16

**US3022021**

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

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

**Generated On: 11 Aug 2021 21:56:25**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-02T14:45:54', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '3d6187ea-3d90-4590-ada2-a141f97d977f' User entered 'None (0)'	System	02 Aug 2020 18:46:28
	System	02 Aug 2020 18:46:28

**US3022021**

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

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

**Generated On: 11 Aug 2021 21:56:25**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-02T14:45:58', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '3d6187ea-3d90-4590-ada2-a141f97d977f' User entered 'None (0)'	System	02 Aug 2020 18:46:28
	System	02 Aug 2020 18:46:28

**US3022021**

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

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

**Generated On: 11 Aug 2021 21:56:25**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-02T14:46:00', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '3d6187ea-3d90-4590-ada2-a141f97d977f' User entered 'None (0)'	System	02 Aug 2020 18:46:28
	System	02 Aug 2020 18:46:28

US3022021

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:56:25

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-02T14:46:02', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '3d6187ea-3d90-4590-ada2-a141f97d977f' User entered 'None (0)'	System	02 Aug 2020 18:46:28
	System	02 Aug 2020 18:46:28

**US3022021**

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

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

**Generated On: 11 Aug 2021 21:56:25**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-02T14:46:05', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '3d6187ea-3d90-4590-ada2-a141f97d977f' User entered 'None (0)'	System	02 Aug 2020 18:46:28
	System	02 Aug 2020 18:46:28

**US3022021**

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

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

**Generated On: 11 Aug 2021 21:56:25**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-02T14:46:07', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '3d6187ea-3d90-4590-ada2-a141f97d977f' User entered 'None (0)'	System	02 Aug 2020 18:46:28
	System	02 Aug 2020 18:46:28

US3022021

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 21:56:25

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)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-02T14:46:12', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '3d6187ea-3d90-4590-ada2-a141f97d977f' User entered 'No (N)'	System	02 Aug 2020 18:46:28
	System	02 Aug 2020 18:46:28

**US3022021**

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

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

**Generated On: 11 Aug 2021 21:56:25**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-02T14:46:27', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '3d6187ea-3d90-4590-ada2-a141f97d977f' User entered '02 Aug 2020 14:46'	System	02 Aug 2020 18:46:28
	System	02 Aug 2020 18:46:28

**US3022021**

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

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

**Generated On: 11 Aug 2021 21:56:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 15:02:16

**US3022021**

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

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

**Generated On: 11 Aug 2021 21:56:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 15:02:16

**US3022021**

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

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

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
Data entry locked.	System	29 Jul 2020 15:02:16
User entered 'Day 6'	System	29 Jul 2020 15:02:16

**US3022021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:56:25**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-03T13:51:47', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '23be3356-ae62-406d-ab99-445666418277' User entered 'None (0)'	System	03 Aug 2020 17:52:12
	System	03 Aug 2020 17:52:12

**US3022021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:56:25**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-03T13:51:50', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '23be3356-ae62-406d-ab99-445666418277' User entered 'None (0)'	System	03 Aug 2020 17:52:12
	System	03 Aug 2020 17:52:12

**US3022021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:56:25**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-03T13:51:52', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '23be3356-ae62-406d-ab99-445666418277' User entered 'None (0)'	System	03 Aug 2020 17:52:12
	System	03 Aug 2020 17:52:12

**US3022021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:56:25**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-03T13:51:55', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '23be3356-ae62-406d-ab99-445666418277' User entered 'None (0)'	System	03 Aug 2020 17:52:12
	System	03 Aug 2020 17:52:12

**US3022021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:56:25**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-03T13:51:57', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '23be3356-ae62-406d-ab99-445666418277' User entered 'None (0)'	System	03 Aug 2020 17:52:12
	System	03 Aug 2020 17:52:12

**US3022021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:56:25**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-03T13:51:59', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '23be3356-ae62-406d-ab99-445666418277' User entered 'None (0)'	System	03 Aug 2020 17:52:12
	System	03 Aug 2020 17:52:12

US3022021

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 21:56:25

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)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-03T13:52:02', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '23be3356-ae62-406d-ab99-445666418277'	System	03 Aug 2020 17:52:12
User entered 'No (N)'	System	03 Aug 2020 17:52:12

**US3022021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-03T13:52:10', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '23be3356-ae62-406d-ab99-445666418277' User entered '03 Aug 2020 13:52'	System	03 Aug 2020 17:52:12
	System	03 Aug 2020 17:52:12

**US3022021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 15:02:16

**US3022021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 15:02:16

**US3022021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
Data entry locked.	System	29 Jul 2020 15:02:16
User entered 'Day 7'	System	29 Jul 2020 15:02:16

**US3022021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:56:25**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-04T12:26:37', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '2684a8fc-4ba8-4367-b7d0-1ec805c3ca7a' User entered 'None (0)'	System	04 Aug 2020 16:27:01
	System	04 Aug 2020 16:27:01

**US3022021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:56:25**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-04T12:26:39', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '2684a8fc-4ba8-4367-b7d0-1ec805c3ca7a' User entered 'None (0)'	System	04 Aug 2020 16:27:01
	System	04 Aug 2020 16:27:01

**US3022021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:56:25**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-04T12:26:42', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '2684a8fc-4ba8-4367-b7d0-1ec805c3ca7a' User entered 'None (0)'	System	04 Aug 2020 16:27:01
	System	04 Aug 2020 16:27:01

**US3022021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:56:25**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-04T12:26:44', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '2684a8fc-4ba8-4367-b7d0-1ec805c3ca7a' User entered 'None (0)'	System	04 Aug 2020 16:27:01
	System	04 Aug 2020 16:27:01

**US3022021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:56:25**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-04T12:26:46', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '2684a8fc-4ba8-4367-b7d0-1ec805c3ca7a' User entered 'None (0)'	System	04 Aug 2020 16:27:01
	System	04 Aug 2020 16:27:01

**US3022021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:56:25**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-04T12:26:48', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '2684a8fc-4ba8-4367-b7d0-1ec805c3ca7a' User entered 'None (0)'	System	04 Aug 2020 16:27:01
	System	04 Aug 2020 16:27:01

US3022021

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 21:56:25

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)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-04T12:26:53', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '2684a8fc-4ba8-4367-b7d0-1ec805c3ca7a' User entered 'No (N)'	System	04 Aug 2020 16:27:01
	System	04 Aug 2020 16:27:01

**US3022021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-08-04T12:26:59', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '2684a8fc-4ba8-4367-b7d0-1ec805c3ca7a' User entered '04 Aug 2020 12:26'	System	04 Aug 2020 16:27:01
	System	04 Aug 2020 16:27:01

**US3022021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '04 Aug 2020 12:00'	System	29 Jul 2020 15:02:16

**US3022021**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 21:56:25**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
User entered '05 Aug 2020 11:59'	System	29 Jul 2020 15:02:16

**US3022021**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:25**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	06 Aug 2020 13:47:10

US3022021

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:56:25

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User closed query 'Per CDM: Visits Safety Call Day 8 and Safety Call Day 36 are both dated 06AUG2020, however it is not possible for these two visits to be on the same day per the schedule of events. Please confirm the date for each visit or amend one of them to 'No' if it was not completed. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 05:07:01
Query 'Per CDM: Visits Safety Call Day 8 and Safety Call Day 36 are both dated 06AUG2020, however it is not possible for these two visits to be on the same day per the schedule of events. Please confirm the date for each visit or amend one of them to 'No' if it was not completed.	(b) (4), (b) (6)	31 Mar 2021 14:49:34
' answered with 'updated ' (Site from DM).		
User opened query 'Per CDM: Visits Safety Call Day 8 and Safety Call Day 36 are both dated 06AUG2020, however it is not possible for these two visits to be on the same day per the schedule of events. Please confirm the date for each visit or amend one of them to 'No' if it was not completed. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 21:14:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '06 Aug 2020'	(b) (4) Shanice Bennett (b) (4) (b) (4)	06 Aug 2020 13:47:10

**US3022021**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:25**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Contact Made (CONTACT MADE)'	Shanice Bennett (b) (4)	06 Aug 2020 13:47:10

**US3022021**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:25**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	Shanice Bennett (b) (4)	06 Aug 2020 13:47:10

**US3022021**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:25**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	06 Aug 2020 13:47:14

**US3022021**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered 'I'	System	06 Aug 2020 13:47:14

**US3022021**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:25**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	12 Aug 2020 20:30:26

US3022021

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:56:25

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User closed query 'Per CDM: Visits Safety Call Day 15 and Safety Call Day 43 are both dated 12AUG2020, however it is not possible for these two visits to be on the same day per the schedule of events. Please confirm the date for each visit or amend one of them to 'No' if it was not completed. '(Site from DM).	(b) (4), (b) (6)	01 Apr 2021 05:12:44
Query 'Per CDM: Visits Safety Call Day 15 and Safety Call Day 43 are both dated 12AUG2020, however it is not possible for these two visits to be on the same day per the schedule of events. Please confirm the date for each visit or amend one of them to 'No' if it was not completed. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 14:38:58
User opened query 'Per CDM: Visits Safety Call Day 15 and Safety Call Day 43 are both dated 12AUG2020, however it is not possible for these two visits to be on the same day per the schedule of events. Please confirm the date for each visit or amend one of them to 'No' if it was not completed. '(Site from DM).	(b) (4), (b) (6)	25 Mar 2021 21:14:56
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '12 Aug 2020'	(b) (4) Shanice Bennett (b) (4) (b) (4)	12 Aug 2020 20:30:26

**US3022021**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:25**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Contact Made (CONTACT MADE)'	Shanice Bennett (b) (4)	12 Aug 2020 20:30:26

**US3022021**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:25**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered empty.	Shanice Bennett (b) (4)	12 Aug 2020 20:30:26

**US3022021**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:25**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	12 Aug 2020 20:30:30

**US3022021**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered 'I'	System	12 Aug 2020 20:30:30

**US3022021**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:25**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 16:15:39

US3022021

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:56:25

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User closed query 'Per CDM: Visits Safety Call Day 22 and Safety Call Day 50 are both dated 19AUG2020, however it is not possible for these two visits to be on the same day per the schedule of events. Please confirm the date for each visit or amend one of them to 'No' if it was not completed. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 13:24:41
Query 'Per CDM: Visits Safety Call Day 22 and Safety Call Day 50 are both dated 19AUG2020, however it is not possible for these two visits to be on the same day per the schedule of events. Please confirm the date for each visit or amend one of them to 'No' if it was not completed. ' answered with 'updated ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 14:39:30
User opened query 'Per CDM: Visits Safety Call Day 22 and Safety Call Day 50 are both dated 19AUG2020, however it is not possible for these two visits to be on the same day per the schedule of events. Please confirm the date for each visit or amend one of them to 'No' if it was not completed. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 21:15:30
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '19 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 16:15:39

**US3022021**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:25**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	19 Aug 2020 16:15:39

**US3022021**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:25**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 16:15:39

**US3022021**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:25**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 16:15:45

**US3022021**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered 'I'	System	19 Aug 2020 16:15:45

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:25**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:03:51

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:25**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:03:51

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:25**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:03:51

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:25**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered 'VISIT2'	System	08 Oct 2020 14:03:51

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	08 Oct 2020 14:04:00

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'No (N)'	(b) (4), (b) (6)	08 Oct 2020 14:04:00

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 14:04:00

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 14:04:00

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered empty.	System	08 Oct 2020 14:04:00

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 14:04:00

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 14:04:00

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 14:04:00

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 14:04:00

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered empty.	System	08 Oct 2020 14:04:00

US3022021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:56:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:04:00

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered empty.	System	08 Oct 2020 14:04:00

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 14:04:00

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered empty.	System	08 Oct 2020 14:04:00

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 14:04:00

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered empty.	System	08 Oct 2020 14:04:00

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	08 Oct 2020 14:04:00

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'No (N)'	(b) (4), (b) (6)	08 Oct 2020 14:04:00

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 14:04:00

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 14:04:00

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered empty.	System	08 Oct 2020 14:04:00

US3022021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:56:25

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 14:04:00

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 14:04:00

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 14:04:00

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 14:04:00

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered empty.	System	08 Oct 2020 14:04:00

US3022021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:56:25

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:04:00

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered empty.	System	08 Oct 2020 14:04:00

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 14:04:00

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered empty.	System	08 Oct 2020 14:04:00

US3022021

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:56:25

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:04:00

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered empty.	System	08 Oct 2020 14:04:00

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:56:25**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:04:05

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:56:25**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 14:04:05

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:25**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:04:12

US3022021

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:56:25

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User closed query 'Per CDM, re-query: Response is noted. Kindly complete the Dosing Discontinuation form as appropriate. Thank you. ' (Site from DM).	(b) (4)	
Query 'Per CDM, re-query: Response is noted. Kindly complete the Dosing Discontinuation form as appropriate. Thank you. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 11:26:14
User opened query 'Per CDM, re-query: Response is noted. Kindly complete the Dosing Discontinuation form as appropriate. Thank you. ' (Site from DM).	Shanice Bennett (b) (4)	18 Nov 2020 12:45:48
User closed query 'Per CDM: Kindly clarify if the participant is not going to receive further doses from the IP. If confirmed, please complete the dosing discontinuation form as appropriate. Thank you. ' (Site from DM).	(b) (4)	
Query 'Per CDM: Kindly clarify if the participant is not going to receive further doses from the IP. If confirmed, please complete the dosing discontinuation form as appropriate. Thank you. ' answered with 'SUBJECT WILL NOT RECEIVE THE 2ND VACCINE.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 10:44:15
User opened query 'Per CDM: Kindly clarify if the participant is not going to receive further doses from the IP. If confirmed, please complete the dosing discontinuation form as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 10:44:15
User closed query 'Per CDM : Please clarify if the reason for discontinuation can be as the one from the list. Kindly correct or clarify and update the dosing discontinuation form accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 20:21:14
Query 'Per CDM : Please clarify if the reason for discontinuation can be as the one from the list. Kindly correct or clarify and update the dosing discontinuation form accordingly.' answered with 'the one chosen is one from the list ' (Site from DM).	(b) (4)	
User opened query 'Per CDM: Kindly clarify if the participant is not going to receive further doses from the IP. If confirmed, please complete the dosing discontinuation form as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 14:21:46
User closed query 'Per CDM : Please clarify if the reason for discontinuation can be as the one from the list. Kindly correct or clarify and update the dosing discontinuation form accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 14:19:41
Query 'Per CDM : Please clarify if the reason for discontinuation can be as the one from the list. Kindly correct or clarify and update the dosing discontinuation form accordingly.' answered with 'the one chosen is one from the list ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 13:38:00

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:56:25

If No, reason not given

Audit	User	Time (GMT)
User opened query 'Per CDM : Please clarify if the reason for discontinuation can be as the one from the list. Kindly correct or clarify and update the dosing discontinuation form accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 12:07:28
User closed query 'Was study treatment given? is No, System however If No, reason not given is not provided. Please review and reconcile.' (Site from System).		08 Oct 2020 14:04:43
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 14:04:43
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	08 Oct 2020 14:04:12
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 14:04:12

US3022021

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:56:25

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)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:04:12

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:25**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered empty.	System	08 Oct 2020 14:04:12

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:25**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:04:12

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:25**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 14:04:12

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:25**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered empty.	System	08 Oct 2020 14:04:12

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:25**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:04:12

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:25**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered empty.	System	08 Oct 2020 14:04:12

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:25**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered empty.	System	08 Oct 2020 14:04:12

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:56:25**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:04:50

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:56:25**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 14:04:50

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:56:25**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 14:04:50

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:56:25**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered empty.	System	08 Oct 2020 14:04:50

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 11 Aug 2021 21:56:25**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 14:04:56

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	08 Oct 2020 14:04:56

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'No (N)'	(b) (4), (b) (6)	08 Oct 2020 14:04:56

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 14:04:56

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered empty.	System	08 Oct 2020 14:04:56

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	08 Oct 2020 14:04:56

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'No (N)'	(b) (4), (b) (6)	08 Oct 2020 14:04:56

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 14:04:56

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered empty.	System	08 Oct 2020 14:04:56

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:25**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 14:05:01

**US3022021**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered 'I'	System	08 Oct 2020 14:05:01

**US3022021**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:25**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:10:24
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 14:49:24
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 14:49:24
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 14:05:25

**US3022021**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:25**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:10:24
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 14:49:24
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 14:49:24
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '06 Aug 2020'	(b) (4), (b) (6)	08 Oct 2020 14:05:25

**US3022021**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:25**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:10:24
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 14:49:24
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 14:49:24
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Oct 2020 14:05:25



**US3022021**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:25**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 14:05:29

**US3022021**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered 'I'	System	08 Oct 2020 14:05:29

**US3022021**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:25**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:10:24
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 14:38:47
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 14:38:47
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 14:05:54

**US3022021**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:25**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:10:24
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 14:38:47
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 14:38:47
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '12 Aug 2020'	(b) (4), (b) (6)	08 Oct 2020 14:05:54

**US3022021**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:25**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:10:24
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 14:38:47
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 14:38:47
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Oct 2020 14:05:54

US3022021

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:56:25

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User closed query 'Per CDM re-query: Per response however kindly update the comment in comment section else clarify.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 07:08:18
Query 'Per CDM re-query: Per response however kindly update the comment in comment section else clarify.' answered with 'call was skipped' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 18:59:10
User opened query 'Per CDM re-query: Per response however kindly update the comment in comment section else clarify.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 18:45:04
User closed query ' Per CDM: Was Contact Attempted? Is recorded as "No". However please provide the reason for contact not made in the Comments section. Else clarify.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 18:45:04
Query ' Per CDM: Was Contact Attempted? Is recorded as "No". However please provide the reason for contact not made in the Comments section. Else clarify.' answered with 'it was skipped' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 13:36:09
User opened query ' Per CDM: Was Contact Attempted? Is recorded as "No". However please provide the reason for contact not made in the Comments section. Else clarify.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 05:07:46
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 14:05:54

**US3022021**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:25**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 14:05:59

**US3022021**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered 'I'	System	08 Oct 2020 14:05:59

**US3022021**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:25**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:10:24
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 14:39:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 14:39:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 14:06:17

**US3022021**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:25**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:10:24
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 14:39:16
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 14:39:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '19 Aug 2020'	(b) (4), (b) (6)	08 Oct 2020 14:06:17

**US3022021**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:25**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:10:24
Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 14:39:16
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 14:39:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Oct 2020 14:06:17

**US3022021**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:25**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 14:06:17

**US3022021**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:25**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 14:06:21

**US3022021**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered 'I'	System	08 Oct 2020 14:06:21

**US3022021**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:25**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 14:06:33

**US3022021**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:25**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:06:33

**US3022021**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:25**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:06:33

**US3022021**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:25**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered 'VISIT3'	System	08 Oct 2020 14:06:33

**US3022021**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:25**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:07:09

**US3022021**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:25**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '28 Sep 2020'	(b) (4), (b) (6)	08 Oct 2020 14:07:09

**US3022021**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:25**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '11:21'	(b) (4), (b) (6)	08 Oct 2020 14:07:09

**US3022021**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:25**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered '28 Sep 2020 11:21'	System	08 Oct 2020 14:07:09

**US3022021**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:25**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '36.6' C	(b) (4), (b) (6)	08 Oct 2020 14:07:09

**US3022021**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:25**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:07:09

**US3022021**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:25**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:07:09

**US3022021**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:25**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '61'	(b) (4), (b) (6)	08 Oct 2020 14:07:09

**US3022021**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:25**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered 'bpm'	System	08 Oct 2020 14:07:09

**US3022021**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:25**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '13'	(b) (4), (b) (6)	08 Oct 2020 14:07:09

**US3022021**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:25**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered 'breaths/min'	System	08 Oct 2020 14:07:09

**US3022021**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:25**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '127'	(b) (4), (b) (6)	08 Oct 2020 14:07:09

**US3022021**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:25**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered 'mmHg'	System	08 Oct 2020 14:07:09

**US3022021**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:25**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '71'	(b) (4), (b) (6)	08 Oct 2020 14:07:09

**US3022021**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:25**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered 'mmHg'	System	08 Oct 2020 14:07:09

**US3022021**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:25**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36

**US3022021**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 21:56:25**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36

**US3022021**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:56:25**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:07:20

**US3022021**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:56:25**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:07:20

**US3022021**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:56:25**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 14:07:38

**US3022021**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:56:25**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '28 Sep 2020'	(b) (4), (b) (6)	08 Oct 2020 14:07:38

**US3022021**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:56:25**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '11:45'	(b) (4), (b) (6)	08 Oct 2020 14:07:38

**US3022021**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:56:25**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered '28 Sep 2020 11:45'	System	08 Oct 2020 14:07:38

**US3022021**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:25**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 14:07:42

**US3022021**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered 'I'	System	08 Oct 2020 14:07:42

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
Data entry locked.	System	29 Jul 2020 15:02:16
User entered 'Day 64'	System	29 Jul 2020 15:02:16

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[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)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-09-29T14:06:14', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: 'f02d9e7e-6692-43e5-82c0-3256ab8e7b41'	System	29 Sep 2020 18:06:33
User entered 'No (N)'	System	29 Sep 2020 18:06:33

US3022021

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:56:25

Have you been exposed to someone with 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)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-09-29T14:06:21', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: 'f02d9e7e-6692-43e5-82c0-3256ab8e7b41'	System	29 Sep 2020 18:06:33
User entered 'No (N)'	System	29 Sep 2020 18:06:33

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-09-29T14:06:30', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: 'f02d9e7e-6692-43e5-82c0-3256ab8e7b41' User entered '29 Sep 2020 14:06:30'	System	29 Sep 2020 18:06:33
	System	29 Sep 2020 18:06:33

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
Data entry locked.	System	29 Jul 2020 15:02:16
User entered '28 Sep 2020 00:01'	System	29 Jul 2020 15:02:16

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
Data entry locked.	System	29 Jul 2020 15:02:16
User entered '02 Oct 2020 23:59'	System	29 Jul 2020 15:02:16

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09
Data entry locked.	System	29 Jul 2020 15:02:16
User entered 'Day 71'	System	29 Jul 2020 15:02:16

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09
Data entry locked.	System	29 Jul 2020 15:02:16
User entered '05 Oct 2020 00:01'	System	29 Jul 2020 15:02:16

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09
Data entry locked.	System	29 Jul 2020 15:02:16
User entered '09 Oct 2020 23:59'	System	29 Jul 2020 15:02:16

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09
Data entry locked.	System	29 Jul 2020 15:02:16
User entered 'Day 78'	System	29 Jul 2020 15:02:16

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09
Data entry locked.	System	29 Jul 2020 15:02:16
User entered '12 Oct 2020 00:01'	System	29 Jul 2020 15:02:16

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09
Data entry locked.	System	29 Jul 2020 15:02:16
User entered '16 Oct 2020 23:59'	System	29 Jul 2020 15:02:16

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
Data entry locked.	System	29 Jul 2020 15:02:16
User entered 'Day 92'	System	29 Jul 2020 15:02:16

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[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)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-10-28T09:54:41', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '5a73eb23-fc2e-45ea-9769-29d690b4eb9a' User entered 'No (N)'	System	28 Oct 2020 14:55:05
	System	28 Oct 2020 14:55:05

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Have you been exposed to someone with 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)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-10-28T09:54:50', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '5a73eb23-fc2e-45ea-9769-29d690b4eb9a'	System	28 Oct 2020 14:55:05
User entered 'No (N)'	System	28 Oct 2020 14:55:05

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2020-10-28T09:55:00', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '5a73eb23-fc2e-45ea-9769-29d690b4eb9a' User entered '28 Oct 2020 09:55:00'	System	28 Oct 2020 14:55:05
	System	28 Oct 2020 14:55:05

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
Data entry locked.	System	29 Jul 2020 15:02:16
User entered '26 Oct 2020 00:01'	System	29 Jul 2020 15:02:16

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:32:00
Data entry locked.	System	29 Jul 2020 15:02:16
User entered '30 Oct 2020 23:59'	System	29 Jul 2020 15:02:16

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09
Data entry locked.	System	29 Jul 2020 15:02:16
User entered 'Day 99'	System	29 Jul 2020 15:02:16

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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**Folder: Safety Follow Up Diary (1)**

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[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

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**Folder: Safety Follow Up Diary (1)**

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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**Folder: Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09
Data entry locked.	System	29 Jul 2020 15:02:16
User entered '02 Nov 2020 00:01'	System	29 Jul 2020 15:02:16

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09
Data entry locked.	System	29 Jul 2020 15:02:16
User entered '06 Nov 2020 23:59'	System	29 Jul 2020 15:02:16

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09
Data entry locked.	System	29 Jul 2020 15:02:16
User entered 'Day 106'	System	29 Jul 2020 15:02:16

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09
Data entry locked.	System	29 Jul 2020 15:02:16
User entered '09 Nov 2020 00:01'	System	29 Jul 2020 15:02:16

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09
Data entry locked.	System	29 Jul 2020 15:02:16
User entered '13 Nov 2020 23:59'	System	29 Jul 2020 15:02:16

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09
Data entry locked.	System	29 Jul 2020 15:02:16
User entered 'Day 113'	System	29 Jul 2020 15:02:16

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 21:56:25**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

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**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 21:56:25**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 21:56:25**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09

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**Folder: Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09
Data entry locked.	System	29 Jul 2020 15:02:16
User entered '16 Nov 2020 00:01'	System	29 Jul 2020 15:02:16

**US3022021**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 02:07:09
Data entry locked.	System	29 Jul 2020 15:02:16
User entered '20 Nov 2020 23:59'	System	29 Jul 2020 15:02:16

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[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 (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2021-01-12T15:57:41', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '58bb77da-6667-409e-9e15-8cdb1e53f291'	System	12 Jan 2021 20:57:58
User entered 'No (N)'	System	12 Jan 2021 20:57:58

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

Have you been exposed to someone with 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 (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2021-01-12T15:57:46', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '58bb77da-6667-409e-9e15-8cdb1e53f291'	System	12 Jan 2021 20:57:58
User entered 'No (N)'	System	12 Jan 2021 20:57:58

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2021-01-12T15:57:55', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '58bb77da-6667-409e-9e15-8cdb1e53f291'	System	12 Jan 2021 20:57:58
User entered '12 Jan 2021 15:57:55'	System	12 Jan 2021 20:57:58

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[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 (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2021-01-25T12:10:25', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '871f5553-30ca-4092-98c9-72a2f6e9f514'	System	25 Jan 2021 17:10:42
User entered 'No (N)'	System	25 Jan 2021 17:10:42

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

Have you been exposed to someone with 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 (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2021-01-25T12:10:31', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '871f5553-30ca-4092-98c9-72a2f6e9f514'	System	25 Jan 2021 17:10:42
User entered 'No (N)'	System	25 Jan 2021 17:10:42

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2021-01-25T12:10:38', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '871f5553-30ca-4092-98c9-72a2f6e9f514'	System	25 Jan 2021 17:10:42
User entered '25 Jan 2021 12:10:38'	System	25 Jan 2021 17:10:42

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[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 (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2021-02-21T12:00:51', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: 'dd0da9e0-faf6-4b73-8c20-bd320994ba60'	System	21 Feb 2021 17:05:14
User entered 'No (N)'	System	21 Feb 2021 17:05:14

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

Have you been exposed to someone with 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 (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2021-02-21T12:01:01', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: 'dd0da9e0-faf6-4b73-8c20-bd320994ba60'	System	21 Feb 2021 17:05:14
User entered 'No (N)'	System	21 Feb 2021 17:05:14

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2021-02-21T12:01:13', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: 'dd0da9e0-faf6-4b73-8c20-bd320994ba60'	System	21 Feb 2021 17:05:14
User entered '21 Feb 2021 12:01:13'	System	21 Feb 2021 17:05:14

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[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 (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2021-03-02T12:00:30-05:00', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: 'ac5722cc-7c33-49ce-8f9c-c57a7d5c974b'	System	02 Mar 2021 17:01:52
User entered 'No (N)'	System	02 Mar 2021 17:01:52

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

Have you been exposed to someone with 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 (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2021-03-02T12:00:35-05:00', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: 'ac5722cc-7c33-49ce-8f9c-c57a7d5c974b'	System	02 Mar 2021 17:01:52
User entered 'No (N)'	System	02 Mar 2021 17:01:52

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2021-03-02T12:00:40-05:00', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: 'ac5722cc-7c33-49ce-8f9c-c57a7d5c974b'	System	02 Mar 2021 17:01:52
User entered '02 Mar 2021 12:00:40'	System	02 Mar 2021 17:01:52

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[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 (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2021-03-05T07:29:08-05:00', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '9060adee-db37-4e60-801f-95cdb6cd938e'	System	05 Mar 2021 12:29:20
User entered 'No (N)'	System	05 Mar 2021 12:29:20

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

Have you been exposed to someone with 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 (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2021-03-05T07:29:13-05:00', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '9060adee-db37-4e60-801f-95cdb6cd938e' User entered 'No (N)'	System	05 Mar 2021 12:29:20
	System	05 Mar 2021 12:29:20

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2021-03-05T07:29:18-05:00', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '9060adee-db37-4e60-801f-95cdb6cd938e' User entered '05 Mar 2021 07:29:18'	System	05 Mar 2021 12:29:20
	System	05 Mar 2021 12:29:20

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[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 (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2021-03-12T08:28:52-05:00', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '17b5b652-f08f-40d1-8033-f775115f0bf2'	System	12 Mar 2021 13:29:05
User entered 'No (N)'	System	12 Mar 2021 13:29:05

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

Have you been exposed to someone with 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 (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2021-03-12T08:28:58-05:00', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '17b5b652-f08f-40d1-8033-f775115f0bf2'	System	12 Mar 2021 13:29:05
User entered 'No (N)'	System	12 Mar 2021 13:29:05

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2021-03-12T08:29:03-05:00', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '17b5b652-f08f-40d1-8033-f775115f0bf2'	System	12 Mar 2021 13:29:05
User entered '12 Mar 2021 08:29:03'	System	12 Mar 2021 13:29:05

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[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 (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2021-03-19T07:55:09-04:00', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '77d4bd1e-b334-4594-a39a-30591e759094'	System	19 Mar 2021 11:55:25
User entered 'No (N)'	System	19 Mar 2021 11:55:25

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

Have you been exposed to someone with 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 (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2021-03-19T07:55:14-04:00', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '77d4bd1e-b334-4594-a39a-30591e759094'	System	19 Mar 2021 11:55:25
User entered 'No (N)'	System	19 Mar 2021 11:55:25

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2021-03-19T07:55:21-04:00', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '77d4bd1e-b334-4594-a39a-30591e759094'	System	19 Mar 2021 11:55:25
User entered '19 Mar 2021 07:55:21'	System	19 Mar 2021 11:55:25

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[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 (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2021-03-26T08:22:29-04:00', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: 'ce6e8e43-a442-4c23-9193-fa8d7db02eba' User entered 'No (N)'	System	26 Mar 2021 12:22:40
	System	26 Mar 2021 12:22:40

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

Have you been exposed to someone with 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 (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2021-03-26T08:22:32-04:00', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: 'ce6e8e43-a442-4c23-9193-fa8d7db02eba' User entered 'No (N)'	System	26 Mar 2021 12:22:40
	System	26 Mar 2021 12:22:40

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2021-03-26T08:22:35-04:00', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: 'ce6e8e43-a442-4c23-9193-fa8d7db02eba' User entered '26 Mar 2021 08:22:35'	System	26 Mar 2021 12:22:40
	System	26 Mar 2021 12:22:40

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[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 (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2021-04-04T08:00:58-04:00', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '3a59e8b1-2071-418c-8b14-a8a6ed907ef3' User entered 'No (N)'	System	04 Apr 2021 12:01:08
	System	04 Apr 2021 12:01:08

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

Have you been exposed to someone with 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 (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2021-04-04T08:01:01-04:00', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '3a59e8b1-2071-418c-8b14-a8a6ed907ef3'	System	04 Apr 2021 12:01:08
User entered 'No (N)'	System	04 Apr 2021 12:01:08

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2021-04-04T08:01:05-04:00', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '3a59e8b1-2071-418c-8b14-a8a6ed907ef3' User entered '04 Apr 2021 08:01:05'	System	04 Apr 2021 12:01:08
	System	04 Apr 2021 12:01:08

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[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 (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2021-04-12T13:14:58-04:00', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: 'dbebe590-083c-489c-8e64-673abcb61df8' User entered 'No (N)'	System	12 Apr 2021 17:21:20
	System	12 Apr 2021 17:21:20

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

Have you been exposed to someone with 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 (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2021-04-12T13:15:01-04:00', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: 'dbebe590-083c-489c-8e64-673abcb61df8' User entered 'No (N)'	System	12 Apr 2021 17:21:20
	System	12 Apr 2021 17:21:20

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2021-04-12T13:15:05-04:00', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: 'dbebe590-083c-489c-8e64-673abcb61df8'	System	12 Apr 2021 17:21:20
User entered '12 Apr 2021 13:15:05'	System	12 Apr 2021 17:21:20

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[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 (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2021-04-16T01:51:16-04:00', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '69036e76-ccf6-4a1d-a7dd-acd9e35bfc81'	System	16 Apr 2021 05:51:37
User entered 'No (N)'	System	16 Apr 2021 05:51:37

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

Have you been exposed to someone with 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 (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2021-04-16T01:51:22-04:00', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '69036e76-ccf6-4a1d-a7dd-acd9e35bfc81'	System	16 Apr 2021 05:51:37
User entered 'No (N)'	System	16 Apr 2021 05:51:37

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2021-04-16T01:51:32-04:00', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '69036e76-ccf6-4a1d-a7dd-acd9e35bfc81' User entered '16 Apr 2021 01:51:32'	System	16 Apr 2021 05:51:37
	System	16 Apr 2021 05:51:37

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[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 (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2021-04-23T10:12:41-04:00', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '1e4b6c60-4628-44c1-ac13-84d24fabb6da' User entered 'No (N)'	System	23 Apr 2021 14:12:55
	System	23 Apr 2021 14:12:55

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

Have you been exposed to someone with 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 (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2021-04-23T10:12:45-04:00', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '1e4b6c60-4628-44c1-ac13-84d24fabb6da' User entered 'No (N)'	System	23 Apr 2021 14:12:55
	System	23 Apr 2021 14:12:55

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2021-04-23T10:12:52-04:00', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '1e4b6c60-4628-44c1-ac13-84d24fabb6da' User entered '23 Apr 2021 10:12:52'	System	23 Apr 2021 14:12:55
	System	23 Apr 2021 14:12:55

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 02:07:09

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 02:07:09

**US3022021**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 21:56:25**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:07:09
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 02:07:09

US3022021

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 21:56:25

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 08:29:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2021-03-02T12:00:51-05:00', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '3891bb93-7bda-4361-b5c9-8774096cfdef'	System	02 Mar 2021 17:03:39
User entered 'Yes (Y)'	System	02 Mar 2021 17:03:39

**US3022021**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 21:56:25**

Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2021-03-02T12:01:02-05:00', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '3891bb93-7bda-4361-b5c9-8774096cfdef' User entered 'No (N)'	System	02 Mar 2021 17:03:39
	System	02 Mar 2021 17:03:39

**US3022021**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 08:29:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (320D33AF-7717-4AE8-ADBF-67EDA1A873FA)', Time: '2021-03-02T12:01:06-05:00', User OID: 'PatientReportedOutcome (US3022021)', ODM File OID: '3891bb93-7bda-4361-b5c9-8774096cfdef' User entered '02 Mar 2021 12:01:06'	System	02 Mar 2021 17:03:39
	System	02 Mar 2021 17:03:39

**US3022021**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:25**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Oct 2020 17:39:30

**US3022021**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:25**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered '20 Oct 2020'	(b) (4), (b) (6)	20 Oct 2020 17:39:30

**US3022021**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:25**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Oct 2020 17:39:30

**US3022021**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:25**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:39:30

**US3022021**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:25**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 13:33:40

**US3022021**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:46:36
User entered 'I'	System	12 Nov 2020 13:33:40

**US3022021**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:25**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:51:48
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Nov 2020 13:23:52

**US3022021**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:25**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:51:48
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '19 Nov 2020'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 13:23:52

**US3022021**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:25**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:51:48
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	30 Nov 2020 13:23:52

**US3022021**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:25**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:51:48
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 13:23:52

**US3022021**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:25**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:51:48
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Nov 2020 13:23:57

**US3022021**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:51:48
User entered 'I'	System	30 Nov 2020 13:23:57

**US3022021**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:25**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:51:48
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Dec 2020 20:03:43

**US3022021**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:25**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:51:48
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '22 Dec 2020'	(b) (4), (b) (6)	22 Dec 2020 20:03:43

**US3022021**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:25**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:51:48
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Dec 2020 20:03:43

**US3022021**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:25**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:51:48
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:03:43

**US3022021**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:25**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:51:48
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:03:47

**US3022021**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:51:48
User entered 'I'	System	22 Dec 2020 20:03:47

**US3022021**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:25**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:51:48
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:33
User entered 'No (N)'	(b) (4), (b) (6)	23 Mar 2021 20:53:56

**US3022021**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:25**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:51:48
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:33
User entered empty.	(b) (4), (b) (6)	23 Mar 2021 20:53:56

**US3022021**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:25**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:51:48
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:33
User entered empty.	(b) (4), (b) (6)	23 Mar 2021 20:53:56

**US3022021**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 21:56:25**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:51:48
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:33
User entered empty.	(b) (4), (b) (6)	23 Mar 2021 20:53:56

**US3022021**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:25**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:51:48
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 22:59:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Mar 2021 20:54:03

**US3022021**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:51:48
User entered 'I'	System	23 Mar 2021 20:54:03

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:25**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Feb 2021 13:39:09

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:25**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 13:39:09

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:25**

[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 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	03 Feb 2021 13:39:09

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 21:56:25**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User entered 'UNBLND_DECIDE'	System	03 Feb 2021 13:39:09

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:56:25**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:41:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 13:39:44

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:56:25**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:41:16
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:10:24
User entered '0'	(b) (4), (b) (6)	01 Apr 2021 13:32:23
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 10:36:16

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:56:25**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:41:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Feb 2021 13:39:44

US3022021

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:56:25

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:41:16
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:10:24
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 12:06:43
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 12:10:35
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 12:10:09
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 08:45:35
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 13:32:23
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 10:36:16

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:56:25**

**Date of unblinding** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:41:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '01 Feb 2021'	(b) (4), (b) (6)	03 Feb 2021 13:39:44

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:56:25**

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:41:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	03 Feb 2021 13:39:44

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:56:25**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:41:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	03 Feb 2021 13:39:44

US3022021

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:56:25

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:41:16
User closed query 'Please confirm that the subject received placebo as their actual dose 2 during part A of the study after receiving mRNA1273 as their actual dose 1 or revise response as necessary.' (Site from CRA).	(b) (4), (b) (6)	03 May 2021 12:21:22
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:10:24
Query 'Please confirm that the subject received placebo as their actual dose 2 during part A of the study after receiving mRNA1273 as their actual dose 1 or revise response as necessary.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	01 Apr 2021 13:32:38
Signature has been broken.	(b) (4), (b) (6)	01 Apr 2021 13:32:23
User entered 'Not Administered (NA)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 13:32:23
User opened query 'Please confirm that the subject received placebo as their actual dose 2 during part A of the study after receiving mRNA1273 as their actual dose 1 or revise response as necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 23:55:41
Query 'Please confirm that the subject's received placebo as their actual dose 2 during part A of the study after receiving mRNA1273 as their actual dose 1 or revise response as necessary.' canceled (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 23:55:25
User opened query 'Please confirm that the subject's received placebo as their actual dose 2 during part A of the study after receiving mRNA1273 as their actual dose 1 or revise response as necessary.' (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 23:55:10
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	03 Feb 2021 13:39:44

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:56:25**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:41:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 13:39:44

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:56:25**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:41:16
User entered empty.	System	03 Feb 2021 13:39:44

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 21:56:25**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:41:16
User entered 'I'	System	03 Feb 2021 13:39:44

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:56:25**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered missing code ND - Not Done.	(b) (4), (b) (6)	03 Feb 2021 13:41:27

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:56:25**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered missing code ND - Not Done.	(b) (4), (b) (6)	03 Feb 2021 13:41:27

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:56:25**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User entered empty.	System	03 Feb 2021 13:41:27
DataPoint set to visible.	System	03 Feb 2021 13:39:44

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:56:25**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered missing code ND - Not Done.	(b) (4), (b) (6)	03 Feb 2021 13:41:27

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:56:25**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered missing code ND - Not Done.	(b) (4), (b) (6)	03 Feb 2021 13:41:27

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:56:25**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User entered empty.	System	03 Feb 2021 13:41:27
DataPoint set to visible.	System	03 Feb 2021 13:39:44

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	03 Feb 2021 13:41:27

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Feb 2021 13:41:27

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 13:41:27

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '11:22'	(b) (4), (b) (6)	03 Feb 2021 13:41:27

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User entered '01 Feb 2021 11:22'	System	03 Feb 2021 13:41:27

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '36.6' C	(b) (4), (b) (6)	03 Feb 2021 13:41:27

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Oral (Oral)'	(b) (4), (b) (6)	03 Feb 2021 13:41:27

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 13:41:27

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '58'	(b) (4), (b) (6)	03 Feb 2021 13:41:27

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User entered 'bpm'	System	03 Feb 2021 13:41:27

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '16'	(b) (4), (b) (6)	03 Feb 2021 13:41:27

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User entered 'breaths/min'	System	03 Feb 2021 13:41:27

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '127'	(b) (4), (b) (6)	03 Feb 2021 13:41:27

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User entered 'mmHg'	System	03 Feb 2021 13:41:27

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '87'	(b) (4), (b) (6)	03 Feb 2021 13:41:27

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User entered 'mmHg'	System	03 Feb 2021 13:41:27

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:56:25**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered missing code ND - Not Done.	(b) (4), (b) (6)	03 Feb 2021 13:41:27

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:56:25**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered missing code ND - Not Done.	(b) (4), (b) (6)	03 Feb 2021 13:41:27

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 21:56:25**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User entered empty.	System	03 Feb 2021 13:41:27
DataPoint set to visible.	System	03 Feb 2021 13:39:44

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	03 Feb 2021 13:41:27

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Feb 2021 13:41:27

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '01 Feb 2021'	(b) (4), (b) (6)	03 Feb 2021 13:41:27

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '13:02'	(b) (4), (b) (6)	03 Feb 2021 13:41:27

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User entered '01 Feb 2021 13:02'	System	03 Feb 2021 13:41:27

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '36.6' C	(b) (4), (b) (6)	03 Feb 2021 13:41:27

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Oral (Oral)'	(b) (4), (b) (6)	03 Feb 2021 13:41:27

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 13:41:27

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '64'	(b) (4), (b) (6)	03 Feb 2021 13:41:27

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User entered 'bpm'	System	03 Feb 2021 13:41:27

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '18'	(b) (4), (b) (6)	03 Feb 2021 13:41:27

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User entered 'breaths/min'	System	03 Feb 2021 13:41:27

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '138'	(b) (4), (b) (6)	03 Feb 2021 13:41:27

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User entered 'mmHg'	System	03 Feb 2021 13:41:27

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '84'	(b) (4), (b) (6)	03 Feb 2021 13:41:27

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User entered 'mmHg'	System	03 Feb 2021 13:41:27

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:56:25**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 13:41:35

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 21:56:25**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 13:41:35

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:25**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Feb 2021 13:41:51

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:25**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 13:41:51

US3022021

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:56:25

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 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered empty.	(b) (4), (b) (6)	03 Feb 2021 13:41:51

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:25**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User entered 'mRNA-1273'	System	03 Feb 2021 13:41:51
DataPoint set to visible.	System	03 Feb 2021 13:39:44

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:25**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '01 Feb 2021'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 13:41:51

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:25**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '12:32'	(b) (4), (b) (6)	03 Feb 2021 13:41:51

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:25**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User entered '01 Feb 2021 12:32'	System	03 Feb 2021 13:41:51

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:25**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	03 Feb 2021 13:41:51

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:25**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User entered 'ONCE'	System	03 Feb 2021 13:41:51

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 21:56:25**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User entered 'INTRAMUSCULAR'	System	03 Feb 2021 13:41:51

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:56:25**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Feb 2021 13:40:02

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:56:25**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '01 Feb 2021'	(b) (4), (b) (6)	03 Feb 2021 13:40:02

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:56:25**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '10:53'	(b) (4), (b) (6)	03 Feb 2021 13:40:02

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 21:56:25**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User entered '01 Feb 2021 10:53'	System	03 Feb 2021 13:40:02

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 21:56:25**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Feb 2021 13:40:11

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 21:56:25**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '01 Feb 2021'	(b) (4), (b) (6)	03 Feb 2021 13:40:11

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 21:56:25**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '11:01'	(b) (4), (b) (6)	03 Feb 2021 13:40:11

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 21:56:25**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User entered '01 Feb 2021 11:01'	System	03 Feb 2021 13:40:11

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:25**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Feb 2021 13:39:51

**US3022021**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 21:56:25**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:36:12
User entered 'I'	System	03 Feb 2021 13:39:51

**US3022021**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 11 Aug 2021 21:56:25**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:09:59
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	17 Sep 2020 18:38:56
User entered 'No (N)'	Shanice Bennett (b) (4)	16 Sep 2020 12:56:48

US3022021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:56:25

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User coded data point as SOC: Vascular disorders, HLGT: Decreased and nonspecific blood pressure disorders and shock, HLT: Vascular hypotensive disorders, PT: Orthostatic hypotension, LLT: Orthostatic hypotension - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 05:42:52
Data point term sent to Coder	(b) (4)	
User entered 'orthostatic hyotension'	Coder Import (b) (4)	18 Sep 2020 05:42:52
	(b) (4)	
	System	17 Sep 2020 18:40:08
	Shanice Bennett (b) (4)	17 Sep 2020 18:39:56
	(b) (4)	

**US3022021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Yes (Y)'	(b) (4) Shanice Bennett (b) (4)	17 Sep 2020 18:39:56

**US3022021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'No (N)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	17 Sep 2020 18:39:56

**US3022021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'No (N)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	17 Sep 2020 18:39:56

**US3022021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '14 Sep 2020'	(b) (4) Shanice Bennett (b) (4) (b) (4)	17 Sep 2020 18:39:56

**US3022021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	17 Sep 2020 18:39:56

**US3022021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:56:25**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 18:39:56

US3022021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:56:25

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User closed query 'Per DM CLR: RQ: Response noted. Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 15:52:19
Query 'Per DM CLR: RQ: Response noted. Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'this is still ongoing per source' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 18:28:46
User opened query 'Per DM CLR: RQ: Response noted. Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	09 Jan 2021 06:53:19
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 05:40:13
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' answered with ' this is still ongoing ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 13:23:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:56:25

[Ongoing?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing or if it occurs intermittently, please update the AE term to include "INTERMITTENT". ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 02:39:18
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 18:40:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Sep 2020 18:40:43
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	17 Sep 2020 18:40:43
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 18:39:56
User entered empty.	Shanice Bennett (b) (4)	17 Sep 2020 18:39:56

**US3022021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:56:25**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	17 Sep 2020 18:39:56

**US3022021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:56:25**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	17 Sep 2020 18:39:56

**US3022021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:56:25**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 18:39:56

**US3022021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Shanice Bennett (b) (4)	17 Sep 2020 18:39:56

**US3022021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'No (N)'	(b) (4) Shanice Bennett (b) (4)	17 Sep 2020 18:39:56

**US3022021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '0'	(b) (4) Shanice Bennett (b) (4) (b) (4)	17 Sep 2020 18:39:56

**US3022021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '0'	(b) (4) Shanice Bennett (b) (4) (b) (4)	17 Sep 2020 18:39:56

**US3022021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '0'	(b) (4) Shanice Bennett (b) (4) (b) (4)	17 Sep 2020 18:39:56

**US3022021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:56:25**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	17 Sep 2020 18:39:56

**US3022021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	17 Sep 2020 18:39:56

**US3022021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	17 Sep 2020 18:39:56

**US3022021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	17 Sep 2020 18:39:56

**US3022021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '0'	(b) (4) Shanice Bennett (b) (4) (b) (4)	17 Sep 2020 18:39:56

**US3022021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '0'	(b) (4) Shanice Bennett (b) (4) (b) (4)	17 Sep 2020 18:39:56

**US3022021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '0'	(b) (4) Shanice Bennett (b) (4) (b) (4)	17 Sep 2020 18:39:56

**US3022021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Not Related (NOT RELATED)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	17 Sep 2020 18:39:56

**US3022021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Not Related (NOT RELATED)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	17 Sep 2020 18:39:56

US3022021

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:56:25

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User closed query 'Per CDM, re-query: Response is noted; however, please note that the dosing discontinuation form is completed. Kindly review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 14:34:50
Query 'Per CDM, re-query: Response is noted; however, please note that the dosing discontinuation form is completed. Kindly review and update as appropriate. ' answered with 'updated' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:03:13
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:03:00
User closed query 'Per CDM: Action taken with investigational product = Dose delayed; however per Visit 2 Day 29, Exposure form the study treatment was not given due to "Physician withheld dose due to Adverse Event". Kindly review and update this field as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 15:36:46
User opened query 'Per CDM, re-query: Response is noted; however, please note that the dosing discontinuation form is completed. Kindly review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 15:36:44
Query 'Per CDM: Action taken with investigational product = Dose delayed; however per Visit 2 Day 29, Exposure form the study treatment was not given due to "Physician withheld dose due to Adverse Event". Kindly review and update this field as appropriate. ' answered with 'this is correct ' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 21:23:15
User opened query 'Per CDM: Action taken with investigational product = Dose delayed; however per Visit 2 Day 29, Exposure form the study treatment was not given due to "Physician withheld dose due to Adverse Event". Kindly review and update this field as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 13:56:49
User entered 'Dose Delayed (DOSE DELAYED)'	Shanice Bennett (b) (4) (b) (4)	17 Sep 2020 18:39:56

**US3022021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:56:25**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'I'	(b) (4) Shanice Bennett (b) (4) (b) (4)	17 Sep 2020 18:39:56

**US3022021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '0'	(b) (4) Shanice Bennett (b) (4) (b) (4)	17 Sep 2020 18:39:56

**US3022021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '0'	(b) (4) Shanice Bennett (b) (4)	17 Sep 2020 18:39:56

**US3022021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	17 Sep 2020 18:39:56

**US3022021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:56:25**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	17 Sep 2020 18:39:56

**US3022021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	17 Sep 2020 18:39:56

**US3022021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Sep 2020 18:39:56

**US3022021**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Sep 2020 18:39:56

US3022021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 21:56:25

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 12:09:59
User closed query 'Per CDM Re-query: Per response however there is no change reflecting in eCRF, kindly review and amend as appropriate else clarify. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 12:24:15
Query 'Per CDM Re-query: Per response however there is no change reflecting in eCRF, kindly review and amend as appropriate else clarify. ' ' answered with 'it is recorded in medical history ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 13:30:27
User opened query 'Per CDM Re-query: Per response however there is no change reflecting in eCRF, kindly review and amend as appropriate else clarify. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 02:54:31
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 02:54:31
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 15:51:52
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 10:14:27

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 11 Aug 2021 21:56:25**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Yes (Y)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:01:38

US3022021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:56:25

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Sep 2020 10:30:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Sep 2020 10:30:56
Data point term sent to Coder	System	02 Sep 2020 17:31:57
Coding entries removed.	Stella Yoon (b) (4)	02 Sep 2020 17:31:37
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Aug 2020 23:43:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Aug 2020 23:43:07
Data point term sent to Coder	System	29 Jul 2020 16:03:54
User entered 'ESTRADOIL PATCH'	Shanice Bennett (b) (4)	29 Jul 2020 16:03:31

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'No (N)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:03:31

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'POST MENOPAUSAL'	(b) (4) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:03:31

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '0.0375'	(b) (4) Shanice Bennett (b) (4)	29 Jul 2020 16:03:31

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'mg (mg)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:03:31

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:56:25**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:03:31

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'twice daily (BID)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:03:31

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:56:25**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:03:31

US3022021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:56:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User closed query 'Per DM CLR: please review the Route as this medication is not typically administered with the dose indicated. Please update route (eg. Transdermal) as appropriate. Otherwise, please confirm route.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Sep 2020 13:20:56
Query 'Per DM CLR: please review the Route as this medication is not typically administered with the dose indicated. Please update route (eg. Transdermal) as appropriate. Otherwise, please confirm route.' answered with 'updated' (Site from DM).	Stella Yoon (b) (4) (b) (4)	02 Sep 2020 17:31:41
User entered 'Transdermal (TRANSDERMAL)' reason for change: Data Entry Error	Stella Yoon (b) (4) (b) (4)	02 Sep 2020 17:31:37
User opened query 'Per DM CLR: please review the Route as this medication is not typically administered with the dose indicated. Please update route (eg. Transdermal) as appropriate. Otherwise, please confirm route.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 15:22:18
User entered 'Topical (TOPICAL)'	Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:03:31

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:56:25**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:03:31

US3022021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:56:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
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)	
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 'CORRECT' (Site from System).	(b) (4), (b) (6)	03 Aug 2020 12:36:08
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).	Shanice Bennett (b) (4)	29 Jul 2020 16:06:04
User entered 'UN UNK 2019'	(b) (4)	
	System	29 Jul 2020 16:03:31
	Shanice Bennett (b) (4)	29 Jul 2020 16:03:31
	(b) (4)	

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '0'	(b) (4) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:03:31

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Yes (Y)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:03:31

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:56:25**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:03:31

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'No (N)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:03:31

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Jul 2020 16:03:31

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jul 2020 16:03:31

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 21:56:25**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Jul 2020 16:03:31

US3022021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:56:25

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAUTERINE CONTRACEPTIVES, PRODUCT: PROGESTERONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 05:54:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 05:54:48
Data point term sent to Coder	System	10 Sep 2020 19:00:38
Coding entries removed.	Shanice Bennett (b) (4)	10 Sep 2020 19:00:07
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: PROGESTOGENS, ATC: PREGNEN (4) DERIVATIVES, PRODUCT: PROGESTERONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Aug 2020 21:40:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Aug 2020 21:40:36
Data point term sent to Coder	System	29 Jul 2020 16:04:55
User entered 'PROGESTERONE'	Shanice Bennett (b) (4)	29 Jul 2020 16:04:02

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'No (N)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:04:02

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'POST MENOPAUSAL'	(b) (4) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:04:02

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '90'	(b) (4) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:04:02

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'mg (mg)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:04:02

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:56:25**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:04:02

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'once daily (QD)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:04:02

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:56:25**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:04:02

US3022021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:56:25

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User closed query 'Per DM CLR: please review the Route as this medication is not typically administered with the dose indicated. Please update route as appropriate. Otherwise, please confirm route.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 13:09:48
Query 'Per DM CLR: please review the Route as this medication is not typically administered with the dose indicated. Please update route as appropriate. Otherwise, please confirm route.' answered with 'updated' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 19:00:23
User entered 'Transdermal (TRANSDERMAL)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Sep 2020 19:00:07
User opened query 'Per DM CLR: please review the Route as this medication is not typically administered with the dose indicated. Please update route as appropriate. Otherwise, please confirm route.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 15:23:50
User entered 'Oral (ORAL)'	Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:04:02

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:56:25**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:04:02

US3022021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:56:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
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)	
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 'CORRECT' (Site from System).	(b) (4), (b) (6)	03 Aug 2020 12:36:13
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).	Shanice Bennett (b) (4)	29 Jul 2020 16:05:56
User entered 'UN UNK 2019'	(b) (4)	
	System	29 Jul 2020 16:04:02
	Shanice Bennett (b) (4)	29 Jul 2020 16:04:02
	(b) (4)	

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '0'	(b) (4) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:04:02

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Yes (Y)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:04:02

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:56:25**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:04:02

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'No (N)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:04:02

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jul 2020 16:04:02

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jul 2020 16:04:02

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 21:56:25**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Jul 2020 16:04:02

US3022021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:56:25

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	10 Aug 2020 18:24:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 18:24:23
Data point term sent to Coder	System	29 Jul 2020 16:04:55
User entered 'TESTOSTERONE'	Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:04:48

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:56:25**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'No (N)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:04:48

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:56:25**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'POST MENOPAUSAL'	(b) (4) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:04:48

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:56:25**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '.75'	(b) (4) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:04:48

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:56:25**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'mg (mg)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:04:48

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:56:25**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:04:48

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:56:25**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'once daily (QD)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:04:48

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:56:25**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:04:48

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:56:25**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Topical (TOPICAL)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:04:48

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:56:25**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:04:48

US3022021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:56:25

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
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)	
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 'CORRECT' (Site from System).	(b) (4), (b) (6)	03 Aug 2020 12:36:17
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).	Shanice Bennett (b) (4)	29 Jul 2020 16:04:51
User entered 'UN UNK 2019'	(b) (4)	
	System	29 Jul 2020 16:04:48
	Shanice Bennett (b) (4)	29 Jul 2020 16:04:48
	(b) (4)	

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:56:25**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '0'	(b) (4) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:04:48

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:56:25**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Yes (Y)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:04:48

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:56:25**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:04:48

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:56:25**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'No (N)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	29 Jul 2020 16:04:48

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:56:25**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jul 2020 16:04:48

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:56:25**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Jul 2020 16:04:48

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 21:56:25**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Jul 2020 16:04:48

US3022021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:56:25

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:35
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User closed query 'Per MM: please confirm if the subject did not meet EC#9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP). If met, please report as possible PD. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 21:10:26
Query 'Per MM: please confirm if the subject did not meet EC#9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP). If met, please report as possible PD. ' answered with 'PD CONFIRMED ' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	22 Sep 2020 19:02:17
User opened query 'Per MM: please confirm if the subject did not meet EC#9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP). If met, please report as possible PD. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 12:06:10
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PERTUSSIS VACCINES, PRODUCT: DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID, PRODUCTSYNONYM: TDAP - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 12:11:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 12:11:41
Data point term sent to Coder	System	27 Aug 2020 18:55:42
Data point term sent to Coder	System	27 Aug 2020 18:54:41

US3022021

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:56:25

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'TETNUS/REDUCED DIPHTHERIA TOXOIDS AND ACELLULAR PERTUSSIS VACCINE'	Shanice Bennett (b) (4) (b) (4)	27 Aug 2020 18:54:33

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:56:25**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:35
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	27 Aug 2020 18:54:33

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:56:25**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:35
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	27 Aug 2020 18:54:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 18:54:50
User entered 'PROPHYLAXIS' reason for change: Data Entry Error	Shanice Bennett (b) (4)	27 Aug 2020 18:54:50
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	27 Aug 2020 18:54:33
User entered empty.	System	27 Aug 2020 18:54:33
	Shanice Bennett (b) (4)	27 Aug 2020 18:54:33
	(b) (4)	

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:56:25**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:35
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '0.5'	Shanice Bennett (b) (4)	27 Aug 2020 18:54:33

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:56:25**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:35
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'mL (mL)'	Shanice Bennett (b) (4)	27 Aug 2020 18:54:33

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:56:25**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:35
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered empty.	Shanice Bennett (b) (4)	27 Aug 2020 18:54:33

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:56:25**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:35
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'once (ONCE)'	Shanice Bennett (b) (4)	27 Aug 2020 18:54:33

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:56:25**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:35
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered empty.	Shanice Bennett (b) (4)	27 Aug 2020 18:54:33

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:56:25**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:35
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Shanice Bennett (b) (4)	27 Aug 2020 18:54:33

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:56:25**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:35
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered empty.	Shanice Bennett (b) (4)	27 Aug 2020 18:54:33

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:56:25**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:35
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '24 Aug 2020'	Shanice Bennett (b) (4)	27 Aug 2020 18:54:33

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:56:25**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:35
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '0'	Shanice Bennett (b) (4)	27 Aug 2020 18:54:33

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:56:25**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:35
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'No (N)'	Shanice Bennett (b) (4)	27 Aug 2020 18:54:33

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:56:25**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:35
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered '24 Aug 2020'	Shanice Bennett (b) (4)	27 Aug 2020 18:54:33

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:56:25**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:35
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'No (N)'	Shanice Bennett (b) (4)	27 Aug 2020 18:54:33

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:56:25**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:35
User entered empty.	System	27 Aug 2020 18:54:33

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:56:25**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:35
User entered empty.	System	27 Aug 2020 18:54:33

**US3022021**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 21:56:25**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:27:35
User entered empty.	System	27 Aug 2020 18:54:33

**US3022021**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 11 Aug 2021 21:56:25**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User entered 'No (N)'	(b) (4) Shanice Bennett (b) (4)	16 Sep 2020 12:56:54

**US3022021**

**Folder: End of Study (1)**

**Form: Dosing Discontinuation**

**Generated On: 11 Aug 2021 21:56:25**

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:55:06
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 15:39:21
User entered '28 Sep 2020'	Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 12:45:39

US3022021

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:56:25

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:55:06
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User closed query 'Per CDM: per End of Study form subject discontinued due to PI decision due to AE. Please review if the reason should be updated to AE. If yes, please record AE number in the other Specify field and update the action taken with investigational product to study drug withdrawn on the AE page. Please also reconcile with the Exposure form at Visit 2 Day 29. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 15:33:52
Query 'Per CDM: per End of Study form subject discontinued due to PI decision due to AE. Please review if the reason should be updated to AE. If yes, please record AE number in the other Specify field and update the action taken with investigational product to study drug withdrawn on the AE page. Please also reconcile with the Exposure form at Visit 2 Day 29. Thank you.' answered with 'updated' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 14:50:36
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 14:50:30
User opened query 'Per CDM: per End of Study form subject discontinued due to PI decision due to AE. Please review if the reason should be updated to AE. If yes, please record AE number in the other Specify field and update the action taken with investigational product to study drug withdrawn on the AE page. Please also reconcile with the Exposure form at Visit 2 Day 29. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 11:00:12
User entered 'Physician decision (specify) (PHYSICIAN DECISION)'	Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 12:45:39

US3022021

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:56:25

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:55:06
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:53:51
User closed query 'Per CDM: Per sponsor review, please update specify field to include AE. (i.e AE#1). Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 08:58:50
Query 'Per CDM: Per sponsor review, please update specify field to include AE. (i.e AE#1). Thank you.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 18:30:40
Signature has been broken.	(b) (4), (b) (6)	04 Mar 2021 18:30:34
User entered 'AE#1' reason for change: Per Query Resolution	(b) (4), (b) (6)	04 Mar 2021 18:30:34
User opened query 'Per CDM: Per sponsor review, please update specify field to include AE. (i.e AE#1). Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 19:08:13
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 15:39:21
User closed query 'Per CDM Re-query: updated noted however, per CCGs please record AE log line number only (i.e. AE #1, etc.)' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 05:38:57
Query 'Per CDM Re-query: updated noted however, per CCGs please record AE log line number only (i.e. AE #1, etc.)' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	25 Nov 2020 20:08:07
User entered '#1' reason for change: Per Query Resolution	Morgan Deal (b) (4)	25 Nov 2020 20:07:58
User opened query 'Per CDM Re-query: updated noted however, per CCGs please record AE log line number only (i.e. AE #1, etc.)' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 01:31:40
User closed query 'Per CDM: Please note that the log line number of the AE needs to be recorded in this field. Kindly update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 01:31:40
Query 'Per CDM: Please note that the log line number of the AE needs to be recorded in this field. Kindly update as appropriate. ' answered with 'updated' (Site from DM).	Shanice Bennett (b) (4)	20 Nov 2020 16:04:20
User entered '#1 DUE TO AE' reason for change: Data Entry Error	Shanice Bennett (b) (4)	20 Nov 2020 16:03:41

US3022021

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:56:25

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User opened query 'Per CDM: Please note that the log line number of the AE needs to be recorded in this field. Kindly update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 15:33:06
User entered 'Due to AE'	Shanice Bennett (b) (4)	18 Nov 2020 12:45:39