

US3732311 (Prod: eStudySite - La Mesa - PPDS)

Generated By: KC Joubran

Generated On: 12 Aug 2021 13:24:11

All time stamps listed in this document are displayed in GMT

US3732311

Form: Participant Creation

Data signed: (b) (4) 26 Feb 2021 01:41:23

Generated On: 12 Aug 2021 13:24:11

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[Participant ID](#)

US3732311

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

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US3732311

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

Date of Birth (MMM yyyy)	(b) (6) 1988
Age	32
Age Units	YEARS
Age (Derived)	32
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) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

Date of Informed Consent ( <i>dd MMM yyyy</i> )	10 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

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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) 26 Feb 2021 01:41:24

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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) 26 Feb 2021 01:41:24

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Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

Condition	BILATERAL BREAST AUGMENTATION SURGERY
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

Condition	MARIJUANA USE
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	10 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	11:19 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 11:19
Height ( <i>xxx.x</i> )	70.0 in
Weight ( <i>xxx.x</i> )	144.8 lb
BMI ( <i>xxx.x</i> )	20.82008 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 01:41:24

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 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) 26 Feb 2021 01:41:24

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Date of assessment (*dd MMM yyyy*) 10 SEP 2020

Is the participant of childbearing potential? Yes ☒  
No ☐

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

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

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) \_\_\_\_\_

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	10 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Feb 2021 01:41:24

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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) 26 Feb 2021 01:41:24

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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)	True
<b>Resides in high density housing</b> (e.g., high rise apartments with shared entrances or elevators)	False
<b>Resides in low density, multi-family setting without</b> (e.g., apartments complex without shared entrances or elevators, duplexes)	False
<b>Resides in a single family home</b> (i.e., detached housing)	False
<b>Other</b>	False
<b>Specify</b>	



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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

What was the date of randomization? (dd MMM yyyy) 10 SEP 2020

What was the participant's randomization number? 112965

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

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) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

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)	10 SEP 2020
Time of assessment (00:00-23:59)	11:19 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 11:19
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

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)	10 SEP 2020
Time of assessment (00:00-23:59)	12:30 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 12:30
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	91 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	61 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

Was the pregnancy test performed? Yes ☐  
No ☒

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

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☒

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

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

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

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) 10 SEP 2020

What was the treatment time? (00:00-23:59) 12:00 (24 HR)

Treatment Date and Time (derived) 10 SEP 2020 12:00

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) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

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

Collection date (dd MMM yyyy)	10 SEP 2020
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Collection time (00:00-23:59)	11:44 (24 HR)
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Collection date and time (derived)	10 SEP 2020 11:44
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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

Collection date (dd MMM yyyy)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:40	10 SEP 2020 11:40
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

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: 12 Aug 2021 13:24:11

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 12:34

PC Open Date & Time

10 SEP 2020 12:20

PC Close Date & Time

10 SEP 2020 14:50

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:24:11

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

10 SEP 2020 15:50

PC Open Date & Time

10 SEP 2020 15:45

PC Close Date & Time

11 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:24:11

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

11 SEP 2020 12:40

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:24:11

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

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Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

12 SEP 2020 13:38

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PC Open Date & Time

12 SEP 2020 12:00

---

PC Close Date & Time

13 SEP 2020 11:59

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US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:24:11

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.1 °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

13 SEP 2020 17:05

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59



US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:24:11

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 12:16

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:24:11

**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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 13:50

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:24:11

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 12:33

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:24:11

**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

10 SEP 2020 12:34

PC Open Date & Time

10 SEP 2020 12:20

PC Close Date & Time

10 SEP 2020 14:50

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:24:11

**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

10 SEP 2020 18:39

PC Open Date & Time

10 SEP 2020 15:45

PC Close Date & Time

11 SEP 2020 11:59

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:24:11

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

3

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 12:46

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:24:11

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

1

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 13:39

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:24:11

**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

13 SEP 2020 17:04

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59



US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:24:11

**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

14 SEP 2020 12:15

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:24:11

**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

15 SEP 2020 12:26

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:24:11

**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

16 SEP 2020 12:33

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:24:11

**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 ☐

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:24:11

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 12:35
PC Open Date & Time	10 SEP 2020 12:20
PC Close Date & Time	10 SEP 2020 14:50

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:24:11

**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 ☐

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:24:11

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

No ☒  
Yes ☐

PC Time stamp	10 SEP 2020 18:39
PC Open Date & Time	10 SEP 2020 15:45
PC Close Date & Time	11 SEP 2020 11:59

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:24:11

**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 ☒



US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:24:11

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 12:47
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:24:11

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)

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:24:11

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 13:39
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:24:11

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 ☒

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:24:11

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 17:04
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:24:11

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 ☒

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:24:11

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

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:24:11

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 ☒



US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:24:11

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 12:26
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:24:11

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 ☒

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:24:11

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 12:33
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3732311

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3732311

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732311

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3732311

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732311

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3732311

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732311

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3732311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

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)	08 OCT 2020
Time of assessment (00:00-23:59)	10:15 (24 HR)
Vital Signs Date and Time (derived)	08 OCT 2020 10:15
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3732311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

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	

US3732311

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 OCT 2020

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

US3732311

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (dd MMM yyyy)	08 OCT 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3732311

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

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?

US3732311

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

08 OCT 2020

Collection time (00:00-23:59)

10:40 (24 HR)

Collection date and time (derived)

08 OCT 2020 10:40



US3732311

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

Collection date (dd MMM yyyy)			08 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:20	08 OCT 2020 10:20
Nasopharyngeal Swab 2	No		

US3732311

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732311

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3732311

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732311

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3732311

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732311

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3732311

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3732311

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 01:41:25

Generated On: 12 Aug 2021 13:24:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3732311

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Feb 2021 01:41:25

Generated On: 12 Aug 2021 13:24:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	05 NOV 2020
Time of assessment (00:00-23:59)	09:05 (24 HR)
Vital Signs Date and Time (derived)	05 NOV 2020 09:05
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	100 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3732311

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 01:41:25

Generated On: 12 Aug 2021 13:24:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 NOV 2020

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

US3732311

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Feb 2021 01:41:25

Generated On: 12 Aug 2021 13:24:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	05 NOV 2020
Collection time (00:00-23:59)	09:20 (24 HR)
Collection date and time (derived)	05 NOV 2020 09:20

US3732311

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:41:25

Generated On: 12 Aug 2021 13:24:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732311

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3732311

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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"/>



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2020 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2020 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°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"/>

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	05 DEC 2020 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	09 DEC 2020 23:59
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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	12 DEC 2020 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 DEC 2020 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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[Patient Cloud Open Date & Time](#)

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19 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

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23 DEC 2020 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	27 DEC 2020 19:19:01
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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"/>

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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[Patient Cloud Close Date & Time](#)

06 JAN 2021 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 JAN 2021 15:47:14
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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 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 JAN 2021 07:19:10
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59



US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 JAN 2021 07:26:48

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 JAN 2021 08:42:56

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 FEB 2021 07:30:17

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 FEB 2021 07:57:17
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

<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	20 FEB 2021 07:09:47
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 16:14:48

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 MAR 2021 08:07:08
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 MAR 2021 08:08:37

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59



US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 MAR 2021 07:59:28
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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 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	30 MAR 2021 17:59:28
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

**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

05 APR 2021 12:06:26

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

**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

10 APR 2021 07:41:08

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

**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

18 APR 2021 13:58:47

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 08:24:00

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

<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	01 MAY 2021 07:06:31
Patient Cloud Open Date & Time	01 MAY 2021 00:01
Patient Cloud Close Date & Time	05 MAY 2021 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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 <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"/>



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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[Patient Cloud Open Date & Time](#)

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08 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 MAY 2021 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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 <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"/>

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

**TIMEPOINT**

DAY 257

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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[Patient Cloud Close Date & Time](#)

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26 MAY 2021 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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 <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"/>

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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"/>

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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[Patient Cloud Close Date & Time](#)

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30 JUN 2021 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°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"/>



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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"/>

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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[Patient Cloud Open Date & Time](#)

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10 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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14 JUL 2021 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

**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 ☐

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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"/>

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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 <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"/>



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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°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"/>

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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"/>

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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[Patient Cloud Close Date & Time](#)

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18 AUG 2021 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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"/>

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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[Patient Cloud Close Date & Time](#)

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25 AUG 2021 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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[Patient Cloud Close Date & Time](#)

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01 SEP 2021 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

**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°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 ☐

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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 <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"/>

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

**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 ☐



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 SEP 2021 23:59
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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	09 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 OCT 2021 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 OCT 2021 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	23 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	27 OCT 2021 23:59
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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

**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 ☐

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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[Patient Cloud Open Date & Time](#)

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06 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 NOV 2021 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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[Patient Cloud Close Date & Time](#)

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24 NOV 2021 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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 <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"/>

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	04 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	08 DEC 2021 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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"/>

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

**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 ☐

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 DEC 2021 23:59
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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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[Patient Cloud Open Date & Time](#)

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15 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 JAN 2022 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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[Patient Cloud Close Date & Time](#)

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26 JAN 2022 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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 <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"/>

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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[Patient Cloud Open Date & Time](#)

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29 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 FEB 2022 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

**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 ☐



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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[Patient Cloud Open Date & Time](#)

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12 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 FEB 2022 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

**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 ☐

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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[Patient Cloud Close Date & Time](#)

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09 MAR 2022 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

**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 ☐



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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[Patient Cloud Open Date & Time](#)

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12 MAR 2022 00:01

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16 MAR 2022 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

**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 ☐

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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23 MAR 2022 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

**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 ☐

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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[Patient Cloud Close Date & Time](#)

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30 MAR 2022 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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 ☐

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

**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 ☐



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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09 APR 2022 00:01

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13 APR 2022 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

**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 ☐

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

**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 ☐ Yes ☐

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

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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[Patient Cloud Close Date & Time](#)

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25 MAY 2022 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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[Patient Cloud Close Date & Time](#)

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01 JUN 2022 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

**TIMEPOINT**

DAY 642

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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[Patient Cloud Close Date & Time](#)

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22 JUN 2022 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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[Patient Cloud Open Date & Time](#)

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25 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 JUN 2022 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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[Patient Cloud Open Date & Time](#)

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09 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 JUL 2022 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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°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 ☐

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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[Patient Cloud Open Date & Time](#)

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16 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 JUL 2022 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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="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"/>

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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23 JUL 2022 00:01

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27 JUL 2022 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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°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"/>



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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30 JUL 2022 00:01

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03 AUG 2022 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

**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°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 ☐

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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06 AUG 2022 00:01

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10 AUG 2022 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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13 AUG 2022 00:01

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17 AUG 2022 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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24 AUG 2022 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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"/>



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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27 AUG 2022 00:01

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31 AUG 2022 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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"/>

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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[Patient Cloud Open Date & Time](#)

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07 SEP 2022 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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10 SEP 2022 00:01

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14 SEP 2022 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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"/>

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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17 SEP 2022 00:01

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21 SEP 2022 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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



**US3732311**

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**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

**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 ☐

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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[Patient Cloud Open Date & Time](#)

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01 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 OCT 2022 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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"/>

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 OCT 2022 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

**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°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 ☐



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

**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 ☐

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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[Patient Cloud Open Date & Time](#)

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29 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 NOV 2022 23:59

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US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

**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°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 ☐

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3732311

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

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"/>

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

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[Patient Cloud Close Date & Time](#)

16 NOV 2022 23:59

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US3732311

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 12 Aug 2021 13:24:11

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 16:14:59



US3732311

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3732311

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732311

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3732311

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732311

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3732311

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3732311

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 21:46:46

Generated On: 12 Aug 2021 13:24:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3732311

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 21:46:46

Generated On: 12 Aug 2021 13:24:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3732311

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 21:46:46

Generated On: 12 Aug 2021 13:24:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3732311

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 21:46:46

Generated On: 12 Aug 2021 13:24:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	06 APR 2021
Time of assessment (00:00-23:59)	10:33 (24 HR)
Vital Signs Date and Time (derived)	06 APR 2021 10:33
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3732311

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 21:46:46

Generated On: 12 Aug 2021 13:24:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 APR 2021

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

US3732311

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 21:46:46

Generated On: 12 Aug 2021 13:24:11

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

Collection date (dd MMM yyyy)	06 APR 2021
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Collection time (00:00-23:59)	10:38 (24 HR)
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Collection date and time (derived)	06 APR 2021 10:38
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US3732311

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 21:46:46

Generated On: 12 Aug 2021 13:24:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3732311**

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

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:24:11**

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*

**US3732311**

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

**Form: Continuing**

**Generated On: 12 Aug 2021 13:24:11**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3732311

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:24:11

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"/>



**US3732311**

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

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

**Generated On: 12 Aug 2021 13:24:11**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3732311

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

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 21:46:46

Generated On: 12 Aug 2021 13:24:11

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

Visit date (dd MMM yyyy)	06 APR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3732311

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

Form: Unblinding

Data signed: (b) (4) 09 Apr 2021 21:46:46

Generated On: 12 Aug 2021 13:24:11

Date of updated informed consent (dd MMM yyyy) 06 APR 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 06 APR 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☐ Placebo ☐ Not Administered ☒

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_

US3732311

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 21:46:46

Generated On: 12 Aug 2021 13:24:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

06 APR 2021

Collection time (00:00-23:59)

10:38 (24 HR)

Collection date and time (derived)

06 APR 2021 10:38

US3732311

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 09 Apr 2021 21:46:46

Generated On: 12 Aug 2021 13:24:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	06 APR 2021
Collection time (00:00 - 23:59)	10:35
Collection Date and Time (derived)	06 APR 2021 10:35

US3732311

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

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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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US3732311

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Feb 2021 01:41:23

Generated On: 12 Aug 2021 13:24:11

AEID	
Adverse event	LEFT AXILLARY LYMPHADENOPATHY AT INJECTION SITE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	18 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	22 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Feb 2021 01:41:23

Generated On: 12 Aug 2021 13:24:11

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	



US3732311

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Feb 2021 01:41:23

Generated On: 12 Aug 2021 13:24:11

AEID

Adverse event

DISPLACED LEFT BREAST  
SILICONE IMPLANT

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

29 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

05 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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EAB) (1725)

US3732311

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Feb 2021 01:41:23

Generated On: 12 Aug 2021 13:24:11

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3732311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

---

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

Yes ☒

No ☐

---

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

---

US3732311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

Name of Medication FISH OIL

Prophylaxis Yes ☒  
No ☐

Indication MALNUTRITION

Dose per administration 2000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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US3732311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3732311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒  
No ☐

Indication VITAMIN DEFICIENCY

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3732311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3732311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

Name of Medication QUETIAPINE

Prophylaxis Yes ☐  
No ☒

Indication INSOMNIA

Dose per administration 25

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) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3732311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication LEFT AXILLARY  
LYMPHADENOPATHY

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	18 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	22 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3732311

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3732311

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 26 Feb 2021 01:41:24

Generated On: 12 Aug 2021 13:24:11

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
05 OCT 2020	BILATERAL BREAST IMPLANT REMOVAL AND LEFT PECTORAL MUSCLE REPAIR	Adverse Event	

US3732311

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 09 Apr 2021 21:46:46

Generated On: 12 Aug 2021 13:24:11

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Date of dosing discontinuation (dd MMM yyyy)	08 OCT 2020
--	-------------

---

Primary reason for dosing discontinuation	AE (specify) <input checked="" type="radio"/>
	SAE (specify) <input type="radio"/>
	Death <input type="radio"/>
	Lost To Follow-up <input type="radio"/>
	Physician decision (specify) <input type="radio"/>
	Pregnancy <input type="radio"/>
	Protocol deviation (specify) <input type="radio"/>
	Study Terminated By Sponsor <input type="radio"/>
	Withdrawal of consent by participant (specify) <input type="radio"/>
	Due to SARS-COV-2 <input type="radio"/>
	Other <input type="radio"/>

---

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify	AE #2
---	-------

---

US3732311

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:24:11

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

US3732311 (Prod: eStudySite - La Mesa - PPDS)



**US3732311**

**Form: Participant Creation**

**Generated On: 12 Aug 2021 13:24:11**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:34:45
User entered 'US3732311'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	10 Sep 2020 18:14:35

US3732311

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:24:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:35:30
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	11 Sep 2020 18:22:27
	(b) (4)	

US3732311

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:35:30
User entered '10 SEP 2020'	RWS_ENDPOINT	10 Sep 2020 18:14:36
	ENDPOINT (b) (4)	

US3732311

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:35:30
User entered 'Clinic (Clinic)'	Lauren Arnett (b) (4)	11 Sep 2020 18:22:27
	(b) (4)	

**US3732311**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:24:11**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User entered 'SCRN'	System	11 Sep 2020 18:22:27

US3732311

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:24:11

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:35:42
User entered (b) (6) 1988'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 18:14:37

US3732311

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:24:11

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:35:42
User entered '32'	Lauren Arnett (b) (4)	10 Sep 2020 18:19:25
	(b) (4)	

**US3732311**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:24:11**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User entered 'YEARS'	System	10 Sep 2020 18:19:25



**US3732311**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:24:11**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User entered '32'	System	10 Sep 2020 18:18:10

US3732311

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:24:11

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:35:42
User entered 'Female (F)'	Lauren Arnett (b) (4)	10 Sep 2020 18:19:25
	(b) (4)	

US3732311

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:24:11

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:35:42
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Lauren Arnett (b) (4)	10 Sep 2020 18:19:25
	(b) (4)	

US3732311

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:24:11

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:35:42
User entered 'I'	Lauren Arnett (b) (4)	10 Sep 2020 18:19:25
	(b) (4)	

US3732311

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:24:11

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:35:42
User entered '0'	Lauren Arnett (b) (4)	10 Sep 2020 18:19:25
	(b) (4)	

US3732311

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:24:11

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:35:42
User entered '0'	Lauren Arnett (b) (4)	10 Sep 2020 18:19:25
	(b) (4)	

US3732311

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:24:11

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:35:42
User entered '0'	Lauren Arnett (b) (4)	10 Sep 2020 18:19:25
	(b) (4)	

US3732311

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:24:11

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:35:42
User entered '0'	Lauren Arnett (b) (4)	10 Sep 2020 18:19:25
	(b) (4)	



US3732311

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:24:11

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:35:42
User entered '0'	Lauren Arnett (b) (4)	10 Sep 2020 18:19:25
	(b) (4)	

US3732311

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:24:11

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:35:42
User entered empty.	Lauren Arnett (b) (4)	10 Sep 2020 18:19:25
	(b) (4)	

US3732311

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:24:11

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:35:42
User entered '0'	Lauren Arnett (b) (4)	10 Sep 2020 18:19:25
	(b) (4)	

US3732311

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:24:11

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:35:42
User entered '0'	Lauren Arnett (b) (4)	10 Sep 2020 18:19:25
	(b) (4)	

US3732311

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:24:11

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:35:48
User entered '10 Sep 2020'	Lauren Arnett (b) (4)	10 Sep 2020 18:18:10
	(b) (4)	

**US3732311**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:24:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User entered 'Sep 2020'	System	10 Sep 2020 18:18:10

**US3732311**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:24:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User entered '2020'	System	10 Sep 2020 18:18:10

US3732311

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:24:11

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:35:48
User entered 'Amendment 3 (3)'	Lauren Arnett (b) (4)	10 Sep 2020 18:18:10
	(b) (4)	



US3732311

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:35:48
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	10 Sep 2020 18:18:10
	(b) (4)	

US3732311

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:24:11

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:35:48
User entered empty.	Lauren Arnett (b) (4)	10 Sep 2020 18:18:10
	(b) (4)	

US3732311

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:24:11

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:35:48
User entered empty.	Lauren Arnett (b) (4)	10 Sep 2020 18:18:10
	(b) (4)	

US3732311

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:24:11

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:35:48
User entered 'No (N)'	Lauren Arnett (b) (4)	10 Sep 2020 18:18:10
	(b) (4)	

US3732311

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:24:11

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:35:48
User entered empty.	RWS_ENDPOINT	10 Sep 2020 18:14:36
	ENDPOINT (b) (4)	

**US3732311**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:24:11**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User entered '1'	System	10 Sep 2020 18:18:16

US3732311

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:36:04
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	10 Sep 2020 18:18:16
	(b) (4)	

US3732311

Folder: Screening

Form: Medical History Summary

Generated On: 12 Aug 2021 13:24:11

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:36:19
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	11 Sep 2020 18:23:09
	(b) (4)	



US3732311

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:24:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:44:38
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 18:25:42
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 18:25:42
	(b) (4)	
Data point term sent to Coder	System	11 Sep 2020 18:24:49
User entered 'insomnia'	Lauren Arnett (b) (4)	11 Sep 2020 18:24:20
	(b) (4)	

US3732311

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:44:38
User entered 'un UNK 1995'	Lauren Arnett (b) (4)	11 Sep 2020 18:24:20
	(b) (4)	

US3732311

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:44:38
User entered '0'	Lauren Arnett (b) (4)	11 Sep 2020 18:24:20
	(b) (4)	

US3732311

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:24:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:44:38
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	11 Sep 2020 18:24:20
	(b) (4)	

US3732311

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:44:38
User entered empty.	Lauren Arnett (b) (4)	11 Sep 2020 18:24:20
	(b) (4)	

US3732311

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:24:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:44:38
User entered '0'	Lauren Arnett (b) (4)	11 Sep 2020 18:24:20
	(b) (4)	

**US3732311**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:24:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User entered 'Jan 1995'	System	11 Sep 2020 18:24:20

**US3732311**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:24:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User entered '1995'	System	11 Sep 2020 18:24:20



**US3732311**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:24:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User entered empty.	System	11 Sep 2020 18:24:20

**US3732311**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:24:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User entered empty.	System	11 Sep 2020 18:24:20

US3732311

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:24:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:44:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Breast therapeutic procedures, HLT: Breast therapeutic procedures NEC, PT: Mammoplasty, LLT: Augmentation mammoplasty - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 18:26:35
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 18:26:35
	(b) (4)	
Data point term sent to Coder	System	11 Sep 2020 18:25:51
User entered 'bilateral breast augmentation surgery'	Lauren Arnett (b) (4)	11 Sep 2020 18:24:51
	(b) (4)	

US3732311

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:44:43
User entered 'un UNK 2017'	Lauren Arnett (b) (4)	11 Sep 2020 18:24:51
	(b) (4)	

US3732311

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:44:43
User entered '0'	Lauren Arnett (b) (4)	11 Sep 2020 18:24:51
	(b) (4)	

US3732311

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:24:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:44:43
User entered 'No (N)'	Lauren Arnett (b) (4)	11 Sep 2020 18:24:51
	(b) (4)	

US3732311

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:44:43
User entered 'un UNK 2017'	Lauren Arnett (b) (4)	11 Sep 2020 18:24:51
	(b) (4)	

US3732311

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:24:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:44:43
User entered '0'	Lauren Arnett (b) (4)	11 Sep 2020 18:24:51
	(b) (4)	



US3732311

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User entered 'Jan 2017'	System	11 Sep 2020 18:24:51

**US3732311**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:24:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User entered '2017'	System	11 Sep 2020 18:24:51

**US3732311**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:24:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User entered 'Jan 2017'	System	11 Sep 2020 18:24:51

US3732311

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User entered '2017'	System	11 Sep 2020 18:24:51

US3732311

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:24:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:44:56
User coded data point as SOC: Social circumstances, HLGT: Lifestyle issues, HLT: Social issues NEC, PT: Substance use, LLT: Marijuana use - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 18:26:36
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 18:26:36
	(b) (4)	
Data point term sent to Coder	System	11 Sep 2020 18:25:52
User entered 'marijuana use'	Lauren Arnett (b) (4)	11 Sep 2020 18:25:04
	(b) (4)	

US3732311

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:44:56
User entered 'un UNK 2015'	Lauren Arnett (b) (4)	11 Sep 2020 18:25:04
	(b) (4)	

US3732311

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:24:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:44:56
User entered '0'	Lauren Arnett (b) (4)	11 Sep 2020 18:25:04
	(b) (4)	

US3732311

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:24:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:44:56
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	11 Sep 2020 18:25:04
	(b) (4)	



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Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:44:56
User entered empty.	Lauren Arnett (b) (4)	11 Sep 2020 18:25:04
	(b) (4)	

US3732311

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:24:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:44:56
User entered '0'	Lauren Arnett (b) (4)	11 Sep 2020 18:25:04
	(b) (4)	

**US3732311**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:24:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User entered 'Jan 2015'	System	11 Sep 2020 18:25:04

**US3732311**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:24:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User entered '2015'	System	11 Sep 2020 18:25:04

**US3732311**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:24:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User entered empty.	System	11 Sep 2020 18:25:04

**US3732311**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:24:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User entered empty.	System	11 Sep 2020 18:25:04

US3732311

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:46:36
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	11 Sep 2020 18:26:10
	(b) (4)	

US3732311

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:46:36
User entered '10 Sep 2020'	Lauren Arnett (b) (4)	11 Sep 2020 18:26:10
	(b) (4)	



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Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:46:36
User entered '11:19'	Lauren Arnett (b) (4)	11 Sep 2020 18:26:10
	(b) (4)	

**US3732311**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:24:11**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User entered '10 Sep 2020 11:19'	System	11 Sep 2020 18:26:10

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Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:11

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:46:36
User entered '70.0' in	Lauren Arnett (b) (4)	11 Sep 2020 18:26:10
	(b) (4)	
DataPoint set to visible.	System	10 Sep 2020 18:18:16

US3732311

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:11

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:46:36
User entered '144.8' lb reason for change: Data Entry Error	Lauren Arnett (b) (4)	11 Sep 2020 18:26:23
	(b) (4)	
User entered '144.8' kg	Lauren Arnett (b) (4)	11 Sep 2020 18:26:10
	(b) (4)	
DataPoint set to visible.	System	10 Sep 2020 18:18:16

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Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:11

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User closed query 'BMI $\geq$ 40 kg/m2 yet participant is not recorded as at risk. Please review and provide, reconcile, or clarification.' (Site from System).	System	11 Sep 2020 18:26:23
Query 'BMI $\geq$ 40 kg/m2 yet participant is not recorded as at risk. Please review and provide, reconcile, or clarification.' answered by data change (Site from System).	System	11 Sep 2020 18:26:23
User entered '20.82008'	System	11 Sep 2020 18:26:23
User opened query 'BMI $\geq$ 40 kg/m2 yet participant is not recorded as at risk. Please review and provide, reconcile, or clarification.' (Site from System).	System	11 Sep 2020 18:26:10
User entered '45.80417'	System	11 Sep 2020 18:26:10
DataPoint set to visible.	System	10 Sep 2020 18:18:16

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Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:11

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User entered 'kg/m2'	System	11 Sep 2020 18:26:10
DataPoint set to visible.	System	10 Sep 2020 18:18:16

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Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:46:36
User entered missing code ND - Not Done.	Lauren Arnett (b) (4)	11 Sep 2020 18:26:10
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:46:36
User entered empty.	Lauren Arnett (b) (4)	11 Sep 2020 18:26:10
	(b) (4)	



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Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:46:36
User entered empty.	Lauren Arnett (b) (4)	11 Sep 2020 18:26:10
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:46:36
User entered missing code ND - Not Done.	Lauren Arnett (b) (4)	11 Sep 2020 18:26:10
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
Query 'Per CDM: Units of measure ( Pulse BPM, Respiratory Rate BREATHS/MIN, Systolic and Diastolic Blood Pressure MMHG ) should not be recorded if value is blank or ND. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 21:01:35
User opened query 'Per CDM: Units of measure ( Pulse BPM, Respiratory Rate BREATHS/MIN, Systolic and Diastolic Blood Pressure MMHG ) should not be recorded if value is blank or ND. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 08:14:31
User entered 'bpm'	System	11 Sep 2020 18:26:10

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Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:46:36
User entered missing code ND - Not Done.	Lauren Arnett (b) (4)	11 Sep 2020 18:26:10
	(b) (4)	

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Folder: Screening

Form: Vital Signs

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[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User entered 'breaths/min'	System	11 Sep 2020 18:26:10

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Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:46:36
User entered missing code ND - Not Done.	Lauren Arnett (b) (4)	11 Sep 2020 18:26:10
	(b) (4)	

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Folder: Screening

Form: Vital Signs

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[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User entered 'mmHg'	System	11 Sep 2020 18:26:10

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Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:46:36
User entered missing code ND - Not Done.	Lauren Arnett (b) (4)	11 Sep 2020 18:26:10
	(b) (4)	



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**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:24:11**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User entered 'mmHg'	System	11 Sep 2020 18:26:10

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Folder: Screening

Form: Vital Signs

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[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14

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Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:11

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14

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Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:24:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:46:55
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	11 Sep 2020 18:26:39
	(b) (4)	

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Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:24:11

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:46:55
User entered '10 Sep 2020'	Lauren Arnett (b) (4)	11 Sep 2020 18:26:39
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:24:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:47:26
User entered '10 Sep 2020'	Lauren Arnett (b) (4)	11 Sep 2020 18:27:20
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:24:11

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:47:26
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	11 Sep 2020 18:27:20
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:24:11

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:47:26
User entered empty.	Lauren Arnett (b) (4)	11 Sep 2020 18:27:20
	(b) (4)	



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Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:24:11

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:47:26
User entered empty.	Lauren Arnett (b) (4)	11 Sep 2020 18:27:20
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:47:26
User entered empty.	Lauren Arnett (b) (4)	11 Sep 2020 18:27:20
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

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Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:47:26
User entered '0'	Lauren Arnett (b) (4)	11 Sep 2020 18:27:20
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:47:26
User entered empty.	Lauren Arnett (b) (4)	11 Sep 2020 18:27:20
	(b) (4)	

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Folder: Screening

Form: Childbearing Potential

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[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:47:26
User entered '0'	Lauren Arnett (b) (4)	11 Sep 2020 18:27:20
	(b) (4)	

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Folder: Screening

Form: Pregnancy Test

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[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:47:33
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	11 Sep 2020 18:28:13
	(b) (4)	

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Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:24:11

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:47:33
User entered '10 Sep 2020'	Lauren Arnett (b) (4)	11 Sep 2020 18:28:13
	(b) (4)	

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Folder: Screening

Form: Pregnancy Test

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[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:47:33
User entered 'Urine (URINE)'	Lauren Arnett (b) (4)	11 Sep 2020 18:28:13
	(b) (4)	



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[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:47:33
User entered 'Negative (NEGATIVE)'	Lauren Arnett (b) (4)	11 Sep 2020 18:28:13
	(b) (4)	

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Folder: Screening

Form: Pregnancy Test

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[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:47:33
User entered 'No (N)'	Lauren Arnett (b) (4)	11 Sep 2020 18:28:13
	(b) (4)	

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Folder: Screening

Form: Pregnancy Test

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[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:47:33
User entered empty.	Lauren Arnett (b) (4)	11 Sep 2020 18:28:13
	(b) (4)	

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Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:24:11

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:47:33
User entered empty.	Lauren Arnett (b) (4)	11 Sep 2020 18:28:13
	(b) (4)	

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**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:24:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User entered empty.	System	11 Sep 2020 18:28:13

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:24:11

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:47:53
User entered 'No (N)'	Lauren Arnett (b) (4)	11 Sep 2020 18:28:41
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:24:11

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:47:53
User entered 'No (N)'	Lauren Arnett (b) (4)	11 Sep 2020 18:28:41
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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**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)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:47:53
User entered 'No (N)'	Lauren Arnett (b) (4)	11 Sep 2020 18:28:41
	(b) (4)	



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Folder: Screening

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**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)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:47:53
User entered 'No (N)'	Lauren Arnett (b) (4)	11 Sep 2020 18:28:41
	(b) (4)	

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[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:47:53
User entered 'No (N)'	Lauren Arnett (b) (4)	11 Sep 2020 18:28:41
	(b) (4)	

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Folder: Screening

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[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)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:47:53
User entered 'No (N)'	Lauren Arnett (b) (4)	11 Sep 2020 18:28:41
	(b) (4)	

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**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)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:47:53
User entered 'No (N)'	Lauren Arnett (b) (4)	11 Sep 2020 18:28:41
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:24:11

**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)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:47:53
User entered 'No (N)'	Lauren Arnett (b) (4)	11 Sep 2020 18:28:41
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[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)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:47:53
User entered 'No (N)'	Lauren Arnett (b) (4)	11 Sep 2020 18:28:41
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:24:11

**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)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:47:53
User entered 'No (N)'	Lauren Arnett (b) (4)	11 Sep 2020 18:28:41
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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**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)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:47:53
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	11 Sep 2020 18:28:41
	(b) (4)	



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Folder: Screening

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:47:53
User entered 'No (N)'	Lauren Arnett (b) (4)	11 Sep 2020 18:28:41
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:47:53
User entered empty.	Lauren Arnett (b) (4)	11 Sep 2020 18:28:41
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
User entered '0'	Lauren Arnett (b) (4)	11 Sep 2020 18:28:41
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:24:11

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:47:53
User entered '0'	Lauren Arnett (b) (4)	11 Sep 2020 18:28:41
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:24:11

**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)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:47:53
User entered 'I'	Lauren Arnett (b) (4)	11 Sep 2020 18:28:41
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:24:11

[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)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:47:53
User entered '0'	Lauren Arnett (b) (4)	11 Sep 2020 18:28:41
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:24:11

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)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:47:53
User entered '0'	Lauren Arnett (b) (4)	11 Sep 2020 18:28:41
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:47:53
User entered '0'	Lauren Arnett (b) (4)	11 Sep 2020 18:28:41
	(b) (4)	



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Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
User entered '0'	Lauren Arnett (b) (4)	11 Sep 2020 18:28:41
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 02:33:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:47:53
User entered empty.	Lauren Arnett (b) (4)	11 Sep 2020 18:28:41
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:24:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:43
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:47:59
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	11 Sep 2020 18:28:57
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:24:11

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:43
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:47:59
User entered '10 Sep 2020'	Lauren Arnett (b) (4)	11 Sep 2020 18:28:57

US3732311

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:43
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:47:59
User entered 'Clinic (Clinic)'	Lauren Arnett (b) (4)	11 Sep 2020 18:28:57

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**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:24:11**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:43
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered 'VISIT1'	System	11 Sep 2020 18:28:57

US3732311

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:50
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:48:46
User entered '10 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 18:34:42

US3732311

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:24:11

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:50
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 22:48:46
User entered '112965'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 18:34:42



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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:24:11

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:50
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:48:46
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 18:34:42

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:24:11

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)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:50
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:48:46
User entered 'No (N)'	Lauren Arnett (b) (4)	11 Sep 2020 18:29:10
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:24:11

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)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:50
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:48:46
User entered 'No (N)'	Lauren Arnett (b) (4)	11 Sep 2020 18:29:10

**US3732311**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 12 Aug 2021 13:24:11**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:50
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:48:46
User entered 'No (N)'	Lauren Arnett (b) (4)	11 Sep 2020 18:29:10

**US3732311**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 12 Aug 2021 13:24:11**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:50
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:48:46
User entered 'No (N)'	Lauren Arnett (b) (4)	11 Sep 2020 18:29:10

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:24:11

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:50
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:48:46
User entered 'No (N)'	Lauren Arnett (b) (4)	11 Sep 2020 18:29:10

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:24:11

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:50
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:31:39
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
User closed query 'Per CDM: This field requires a Yes or No response. Please complete. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 12:07:50
Query 'Per CDM: This field requires a Yes or No response. Please complete. ' answered with 'data has been entered' (Site from DM).	Amara Yilmaz (b) (4)	09 Dec 2020 00:32:50
User entered 'No (N)'	Amara Yilmaz (b) (4)	09 Dec 2020 00:32:07
User opened query 'Per CDM: This field requires a Yes or No response. Please complete. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 22:29:06
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 06:02:21
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:02:20

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:24:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:49:08
User entered missing code ND - Not Done.	Lauren Arnett (b) (4)	11 Sep 2020 18:31:50



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:24:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:49:10
User entered missing code ND - Not Done.	Lauren Arnett (b) (4)	11 Sep 2020 18:31:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:24:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:49:08
User entered missing code ND - Not Done.	Lauren Arnett (b) (4)	11 Sep 2020 18:31:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:24:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:49:10
User entered missing code ND - Not Done.	Lauren Arnett (b) (4)	11 Sep 2020 18:31:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User accepted default value 'Pre-Dose (PREDOSE)'	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 18:31:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:49:05
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	11 Sep 2020 18:31:50
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:49:05
User entered '10 Sep 2020'	Lauren Arnett (b) (4)	11 Sep 2020 18:31:50
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:49:05
User entered '11:19'	Lauren Arnett (b) (4)	11 Sep 2020 18:31:50
	(b) (4)	

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:24:11**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered '10 Sep 2020 11:19'	System	11 Sep 2020 18:31:50



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:49:05
User entered '97.9' F	Lauren Arnett (b) (4)	11 Sep 2020 18:31:50
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:49:05
User entered 'Oral (Oral)'	Lauren Arnett (b) (4)	11 Sep 2020 18:31:50
	(b) (4)	

US3732311

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:49:05
User entered empty.	Lauren Arnett (b) (4)	11 Sep 2020 18:31:50
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:49:05
User entered '73'	Lauren Arnett (b) (4)	11 Sep 2020 18:31:50

US3732311

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered 'bpm'	System	11 Sep 2020 18:31:50

US3732311

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:49:05
User entered '14'	Lauren Arnett (b) (4)	11 Sep 2020 18:31:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered 'breaths/min'	System	11 Sep 2020 18:31:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:49:05
User entered '109'	Lauren Arnett (b) (4)	11 Sep 2020 18:31:50
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered 'mmHg'	System	11 Sep 2020 18:31:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:49:05
User entered '68'	Lauren Arnett (b) (4)	11 Sep 2020 18:31:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered 'mmHg'	System	11 Sep 2020 18:31:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:24:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:49:08
User entered missing code ND - Not Done.	Lauren Arnett (b) (4)	11 Sep 2020 18:31:50

US3732311

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:24:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:49:10
User entered missing code ND - Not Done.	Lauren Arnett (b) (4)	11 Sep 2020 18:31:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User accepted default value 'Post-Dose (POSTDOSE)'	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 18:31:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:54:26
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	11 Sep 2020 18:31:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:54:26
User entered '10 Sep 2020'	Lauren Arnett (b) (4)	11 Sep 2020 18:31:50
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:11

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:54:26
User entered '12:30'	Lauren Arnett (b) (4)	11 Sep 2020 18:31:50
	(b) (4)	

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:24:11**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered '10 Sep 2020 12:30'	System	11 Sep 2020 18:31:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:54:26
User entered '98.3' F	Lauren Arnett (b) (4)	11 Sep 2020 18:31:50
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:54:26
User entered 'Oral (Oral)'	Lauren Arnett (b) (4)	11 Sep 2020 18:31:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:54:26
User entered empty.	Lauren Arnett (b) (4)	11 Sep 2020 18:31:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:54:26
User entered '68'	Lauren Arnett (b) (4)	11 Sep 2020 18:31:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered 'bpm'	System	11 Sep 2020 18:31:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:54:26
User entered '16'	Lauren Arnett (b) (4)	11 Sep 2020 18:31:50



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered 'breaths/min'	System	11 Sep 2020 18:31:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:54:26
User entered '91'	Lauren Arnett (b) (4)	11 Sep 2020 18:31:50
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered 'mmHg'	System	11 Sep 2020 18:31:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:54:26
User entered '61'	Lauren Arnett (b) (4)	11 Sep 2020 18:31:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered 'mmHg'	System	11 Sep 2020 18:31:50

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:24:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:42:03
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:49:29
User entered 'No (N)'	Lauren Arnett (b) (4)	11 Sep 2020 18:31:56

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:24:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:42:03
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:49:29
User entered empty.	Lauren Arnett (b) (4)	11 Sep 2020 18:31:56

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:24:11

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:42:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:49:38
User entered 'No (N)'	Lauren Arnett (b) (4)	11 Sep 2020 18:32:12



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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:24:11

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:42:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:49:38
User entered empty.	Lauren Arnett (b) (4)	11 Sep 2020 18:32:12
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:24:11

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:42:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:49:38
User entered empty.	Lauren Arnett (b) (4)	11 Sep 2020 18:32:12

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:24:11

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:42:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:49:38
User entered empty.	Lauren Arnett (b) (4)	11 Sep 2020 18:32:12
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:24:11

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:42:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 22:49:38
User closed query 'per CDM: please select yes or no for this field' (Site from DM).		09 Nov 2020 21:18:10
Query 'per CDM: please select yes or no for this field' answered with 'updated ' (Site from DM).	Lauren Arnett (b) (4)	09 Nov 2020 21:11:02
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Lauren Arnett (b) (4)	09 Nov 2020 21:10:55
User opened query 'per CDM: please select yes or no for this field' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 15:35:13
User entered empty.	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 18:32:12

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**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:24:11**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:42:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:49:38
User entered empty.	Lauren Arnett (b) (4)	11 Sep 2020 18:32:12

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:24:11

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:42:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:49:38
User entered empty.	Lauren Arnett (b) (4)	11 Sep 2020 18:32:12
	(b) (4)	

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**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:24:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:42:12
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered empty.	System	11 Sep 2020 18:32:12

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:24:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:42:16
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:50:08
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	10 Sep 2020 19:07:51



US3732311

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:24:11

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:42:16
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:50:08
User entered empty.	Lauren Arnett (b) (4)	10 Sep 2020 19:07:51
	(b) (4)	

US3732311

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:24:11

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)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:42:16
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:50:08
User entered empty.	Lauren Arnett (b) (4)	10 Sep 2020 19:07:51
	(b) (4)	

US3732311

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:24:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:42:16
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 19:07:51

US3732311

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:24:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:42:16
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:50:08
User entered '10 Sep 2020'	Lauren Arnett (b) (4)	10 Sep 2020 19:07:51
	(b) (4)	

US3732311

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:24:11

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:42:16
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:50:08
User entered '12:00'	Lauren Arnett (b) (4)	10 Sep 2020 19:07:51
	(b) (4)	

**US3732311**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:24:11**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:42:16
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered '10 Sep 2020 12:00'	System	10 Sep 2020 19:07:51

US3732311

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:24:11

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:42:16
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:50:08
User entered 'Left Arm (LEFT ARM)'	Lauren Arnett (b) (4)	10 Sep 2020 19:07:51

US3732311

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:24:11

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:42:16
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:50:08
User entered 'ONCE'	System	10 Sep 2020 19:07:51



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:24:11

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:42:16
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 19:07:51

US3732311

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:24:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:42:19
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:50:38
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	11 Sep 2020 18:32:25

US3732311

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:24:11

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:42:19
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:50:38
User entered '10 Sep 2020'	Lauren Arnett (b) (4)	11 Sep 2020 18:32:25

US3732311

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:24:11

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:42:19
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:50:38
User entered '11:44'	Lauren Arnett (b) (4)	11 Sep 2020 18:32:25
	(b) (4)	

**US3732311**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:24:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:42:19
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered '10 Sep 2020 11:44'	System	11 Sep 2020 18:32:25

US3732311

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:24:11

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:42:23
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:50:16
User entered '10 Sep 2020'	Lauren Arnett (b) (4)	11 Sep 2020 18:32:39

US3732311

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:24:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:42:23
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 18:32:39

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:24:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:42:23
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:50:16
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	11 Sep 2020 18:32:39
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:24:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:42:23
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:50:16
User entered '11:40'	Lauren Arnett (b) (4)	11 Sep 2020 18:32:39
	(b) (4)	

**US3732311**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:24:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:42:23
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered '10 Sep 2020 11:40'	System	11 Sep 2020 18:32:39

US3732311

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:24:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:42:23
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 18:32:39

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:24:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:42:23
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:50:16
User entered 'No (N)'	Lauren Arnett (b) (4)	11 Sep 2020 18:32:39
	(b) (4)	

**US3732311**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 13:24:11**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:42:23
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 22:50:16
User entered empty.	Lauren Arnett (b) (4)	11 Sep 2020 18:32:39
	(b) (4)	

**US3732311**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 13:24:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:42:23
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered empty.	System	11 Sep 2020 18:32:39

US3732311

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:24:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:03
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 22:53:52
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 18:32:43

**US3732311**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:24:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:41:03
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered 'l'	System	11 Sep 2020 18:32:43



US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:24:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
Data entry locked.	System	10 Sep 2020 19:07:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:24:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-10T12:33:54', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '47df10c9-dbeb-4e07-8968-fd174d849b40' User entered 'Yes (Y)'	System	10 Sep 2020 19:34:16
	System	10 Sep 2020 19:34:16

US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:24:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-10T12:34:01', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '47df10c9-dbeb-4e07-8968-fd174d849b40' User entered '98.3'	System	10 Sep 2020 19:34:16
	System	10 Sep 2020 19:34:16

US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-10T12:34:04', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '47df10c9-dbeb-4e07-8968-fd174d849b40'	System	10 Sep 2020 19:34:16
User entered 'No (N)'	System	10 Sep 2020 19:34:16

**US3732311**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-10T12:34:12', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '47df10c9-dbeb-4e07-8968-fd174d849b40' User entered '10 Sep 2020 12:34'	System	10 Sep 2020 19:34:16
	System	10 Sep 2020 19:34:16

**US3732311**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '10 Sep 2020 12:20'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '10 Sep 2020 14:50'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:24:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
Data entry locked.	System	10 Sep 2020 19:07:51
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 19:07:51



US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:24:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-10T15:49:56', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '1608fed0-7ad7-4976-ac2c-fae92101fc59' User entered 'Yes (Y)'	System	10 Sep 2020 22:50:11
	System	10 Sep 2020 22:50:11

US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:24:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-10T15:50:00', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '1608fed0-7ad7-4976-ac2c-fae92101fc59' User entered '98.4'	System	10 Sep 2020 22:50:11
	System	10 Sep 2020 22:50:11

US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-10T15:50:04', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '1608fed0-7ad7-4976-ac2c-fae92101fc59'	System	10 Sep 2020 22:50:11
User entered 'No (N)'	System	10 Sep 2020 22:50:11

**US3732311**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-10T15:50:09', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '1608fed0-7ad7-4976-ac2c-fae92101fc59' User entered '10 Sep 2020 15:50'	System	10 Sep 2020 22:50:11
	System	10 Sep 2020 22:50:11

US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '10 Sep 2020 15:45'	System	10 Sep 2020 19:07:51

**US3732311**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:24:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
Data entry locked.	System	10 Sep 2020 19:07:51
User entered 'Day 2'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:24:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-11T12:39:05', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'b4679508-6740-4157-9f66-f3bbc8d489ec' User entered 'Yes (Y)'	System	11 Sep 2020 19:40:42
	System	11 Sep 2020 19:40:42



US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:24:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-11T12:40:32', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'b4679508-6740-4157-9f66-f3bbc8d489ec' User entered '97.5'	System	11 Sep 2020 19:40:42
	System	11 Sep 2020 19:40:42

US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-11T12:40:34', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'b4679508-6740-4157-9f66-f3bbc8d489ec' User entered 'No (N)'	System	11 Sep 2020 19:40:42
	System	11 Sep 2020 19:40:42

**US3732311**

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

**Form: Temperature\_Day(2)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-11T12:40:38', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'b4679508-6740-4157-9f66-f3bbc8d489ec' User entered '11 Sep 2020 12:40'	System	11 Sep 2020 19:40:42
	System	11 Sep 2020 19:40:42

US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:24:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
Data entry locked.	System	10 Sep 2020 19:07:51
User entered 'Day 3'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:24:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-12T13:37:48', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'c5c6b873-594b-4790-b170-b9ea68d73544'	System	12 Sep 2020 20:38:36
User entered 'Yes (Y)'	System	12 Sep 2020 20:38:36

US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:24:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-12T13:38:25', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'c5c6b873-594b-4790-b170-b9ea68d73544'	System	12 Sep 2020 20:38:36
User entered '98.6'	System	12 Sep 2020 20:38:36



US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-12T13:38:29', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'c5c6b873-594b-4790-b170-b9ea68d73544'	System	12 Sep 2020 20:38:36
User entered 'No (N)'	System	12 Sep 2020 20:38:36

**US3732311**

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

**Form: Temperature\_Day(3)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-12T13:38:33', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'c5c6b873-594b-4790-b170-b9ea68d73544'	System	12 Sep 2020 20:38:36
User entered '12 Sep 2020 13:38'	System	12 Sep 2020 20:38:36

**US3732311**

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

**Form: Temperature\_Day(3)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:24:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
Data entry locked.	System	10 Sep 2020 19:07:51
User entered 'Day 4'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:24:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-13T17:04:25', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '107046bd-bdf3-4737-b722-34c59a20f2aa' User entered 'Yes (Y)'	System	14 Sep 2020 00:07:23
	System	14 Sep 2020 00:07:23

US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:24:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-13T17:04:54', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '107046bd-bdf3-4737-b722-34c59a20f2aa' User entered '99.1'	System	14 Sep 2020 00:07:23
	System	14 Sep 2020 00:07:23

US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-13T17:04:57', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '107046bd-bdf3-4737-b722-34c59a20f2aa'	System	14 Sep 2020 00:07:23
User entered 'No (N)'	System	14 Sep 2020 00:07:23



**US3732311**

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

**Form: Temperature\_Day(4)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-13T17:05:00', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '107046bd-bdf3-4737-b722-34c59a20f2aa' User entered '13 Sep 2020 17:05'	System	14 Sep 2020 00:07:23
	System	14 Sep 2020 00:07:23

US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 19:07:51

**US3732311**

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

**Form: Temperature\_Day(4)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:24:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
Data entry locked.	System	10 Sep 2020 19:07:51
User entered 'Day 5'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:24:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-14T12:15:24', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '81c987a8-71f9-4f58-8fb0-2a5759166a0b' User entered 'Yes (Y)'	System	14 Sep 2020 19:16:33
	System	14 Sep 2020 19:16:33

US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:24:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-14T12:16:25', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '81c987a8-71f9-4f58-8fb0-2a5759166a0b' User entered '98.3'	System	14 Sep 2020 19:16:33
	System	14 Sep 2020 19:16:33

US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-14T12:16:27', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '81c987a8-71f9-4f58-8fb0-2a5759166a0b' User entered 'No (N)'	System	14 Sep 2020 19:16:33
	System	14 Sep 2020 19:16:33

**US3732311**

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

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

**Generated On: 12 Aug 2021 13:24:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-14T12:16:30', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '81c987a8-71f9-4f58-8fb0-2a5759166a0b' User entered '14 Sep 2020 12:16'	System	14 Sep 2020 19:16:33
	System	14 Sep 2020 19:16:33



**US3732311**

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

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

**Generated On: 12 Aug 2021 13:24:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:24:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
Data entry locked.	System	10 Sep 2020 19:07:51
User entered 'Day 6'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:24:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-15T13:48:19', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'ed71408d-c386-4b94-8125-4875b46a584a' User entered 'Yes (Y)'	System	15 Sep 2020 20:50:22
	System	15 Sep 2020 20:50:22

US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:24:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-15T13:50:12', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'ed71408d-c386-4b94-8125-4875b46a584a' User entered '98.6'	System	15 Sep 2020 20:50:22
	System	15 Sep 2020 20:50:22

US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-15T13:50:15', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'ed71408d-c386-4b94-8125-4875b46a584a'	System	15 Sep 2020 20:50:22
User entered 'No (N)'	System	15 Sep 2020 20:50:22

**US3732311**

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

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

**Generated On: 12 Aug 2021 13:24:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-15T13:50:20', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'ed71408d-c386-4b94-8125-4875b46a584a' User entered '15 Sep 2020 13:50'	System	15 Sep 2020 20:50:22
	System	15 Sep 2020 20:50:22

**US3732311**

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

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

**Generated On: 12 Aug 2021 13:24:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 19:07:51



US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:24:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
Data entry locked.	System	10 Sep 2020 19:07:51
User entered 'Day 7'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:24:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-16T12:33:23', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '40044d47-a83a-4f0d-b94a-9deab77e0ab4' User entered 'Yes (Y)'	System	16 Sep 2020 19:33:32
	System	16 Sep 2020 19:33:32

US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:24:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-16T12:33:26', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '40044d47-a83a-4f0d-b94a-9deab77e0ab4' User entered '97.8'	System	16 Sep 2020 19:33:32
	System	16 Sep 2020 19:33:32

US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-16T12:33:28', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '40044d47-a83a-4f0d-b94a-9deab77e0ab4' User entered 'No (N)'	System	16 Sep 2020 19:33:32
	System	16 Sep 2020 19:33:32

**US3732311**

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

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

**Generated On: 12 Aug 2021 13:24:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-16T12:33:29', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '40044d47-a83a-4f0d-b94a-9deab77e0ab4' User entered '16 Sep 2020 12:33'	System	16 Sep 2020 19:33:32
	System	16 Sep 2020 19:33:32

US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 19:07:51



US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:24:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
Data entry locked.	System	10 Sep 2020 19:07:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-10T12:34:27', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '29f5dfdd-6d2c-4647-a891-bbdb828ca0a5' User entered 'None (1)'	System	10 Sep 2020 19:34:59
	System	10 Sep 2020 19:34:59

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:24:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-10T12:34:45', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '29f5dfdd-6d2c-4647-a891-bbdb828ca0a5' User entered 'No (N)'	System	10 Sep 2020 19:34:59
	System	10 Sep 2020 19:34:59

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-10T12:34:47', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '29f5dfdd-6d2c-4647-a891-bbdb828ca0a5' User entered 'No (N)'	System	10 Sep 2020 19:34:59
	System	10 Sep 2020 19:34:59

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-10T12:34:52', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '29f5dfdd-6d2c-4647-a891-bbdb828ca0a5' User entered 'None (1)'	System	10 Sep 2020 19:34:59
	System	10 Sep 2020 19:34:59

**US3732311**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-10T12:34:55', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '29f5dfdd-6d2c-4647-a891-bbdb828ca0a5' User entered '10 Sep 2020 12:34'	System	10 Sep 2020 19:34:59
	System	10 Sep 2020 19:34:59

**US3732311**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '10 Sep 2020 12:20'	System	10 Sep 2020 19:07:51

**US3732311**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '10 Sep 2020 14:50'	System	10 Sep 2020 19:07:51



US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:24:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
Data entry locked.	System	10 Sep 2020 19:07:51
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-10T15:50:40', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '05192d8d-1995-4433-baac-694412b37538'	System	11 Sep 2020 01:39:32
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 01:39:32

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:24:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-10T18:38:58', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '05192d8d-1995-4433-baac-694412b37538' User entered 'No (N)'	System	11 Sep 2020 01:39:32
	System	11 Sep 2020 01:39:32

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-10T18:39:01', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '05192d8d-1995-4433-baac-694412b37538' User entered 'No (N)'	System	11 Sep 2020 01:39:32
	System	11 Sep 2020 01:39:32

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-10T18:39:09', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '05192d8d-1995-4433-baac-694412b37538'	System	11 Sep 2020 01:39:32
User entered 'None (1)'	System	11 Sep 2020 01:39:32

**US3732311**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-10T18:39:19', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '05192d8d-1995-4433-baac-694412b37538' User entered '10 Sep 2020 18:39'	System	11 Sep 2020 01:39:32
	System	11 Sep 2020 01:39:32

**US3732311**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '10 Sep 2020 15:45'	System	10 Sep 2020 19:07:51

**US3732311**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 19:07:51



US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:24:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
Data entry locked.	System	10 Sep 2020 19:07:51
User entered 'Day 2'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-11T12:46:48', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'dabc923b-07db-4ba6-8503-31259a2fb74c'	System	11 Sep 2020 19:46:59
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 19:46:59

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:24:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-11T12:40:57', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'dabc923b-07db-4ba6-8503-31259a2fb74c' User entered 'No (N)'	System	11 Sep 2020 19:46:59
	System	11 Sep 2020 19:46:59

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-11T12:41:00', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'dabc923b-07db-4ba6-8503-31259a2fb74c' User entered 'Yes (Y)'	System	11 Sep 2020 19:46:59
	System	11 Sep 2020 19:46:59

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:24:11

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-11T12:46:21', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'dabc923b-07db-4ba6-8503-31259a2fb74c' User entered '3'	System	11 Sep 2020 19:46:59
	System	11 Sep 2020 19:46:59

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-11T12:46:26', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'dabc923b-07db-4ba6-8503-31259a2fb74c' User entered 'None (1)'	System	11 Sep 2020 19:46:59
	System	11 Sep 2020 19:46:59

**US3732311**

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

**Form: Injection Site\_Day(2)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-11T12:46:55', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'dabc923b-07db-4ba6-8503-31259a2fb74c' User entered '11 Sep 2020 12:46'	System	11 Sep 2020 19:46:59
	System	11 Sep 2020 19:46:59

**US3732311**

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

**Form: Injection Site\_Day(2)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 19:07:51



**US3732311**

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

**Form: Injection Site\_Day(2)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:24:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
Data entry locked.	System	10 Sep 2020 19:07:51
User entered 'Day 3'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-12T13:38:38', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '8225bb4d-16f6-46aa-86bb-f6363880151f'	System	12 Sep 2020 20:39:10
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 20:39:10

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:24:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-12T13:38:41', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '8225bb4d-16f6-46aa-86bb-f6363880151f' User entered 'No (N)'	System	12 Sep 2020 20:39:10
	System	12 Sep 2020 20:39:10

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-12T13:38:45', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '8225bb4d-16f6-46aa-86bb-f6363880151f' User entered 'Yes (Y)'	System	12 Sep 2020 20:39:10
	System	12 Sep 2020 20:39:10

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:24:11

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-12T13:38:57', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '8225bb4d-16f6-46aa-86bb-f6363880151f' User entered '1'	System	12 Sep 2020 20:39:10
	System	12 Sep 2020 20:39:10

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-12T13:38:59', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '8225bb4d-16f6-46aa-86bb-f6363880151f' User entered 'None (1)'	System	12 Sep 2020 20:39:10
	System	12 Sep 2020 20:39:10

**US3732311**

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

**Form: Injection Site\_Day(3)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-12T13:39:07', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '8225bb4d-16f6-46aa-86bb-f6363880151f' User entered '12 Sep 2020 13:39'	System	12 Sep 2020 20:39:10
	System	12 Sep 2020 20:39:10



US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:24:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 19:07:51

**US3732311**

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

**Form: Injection Site\_Day(3)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:24:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
Data entry locked.	System	10 Sep 2020 19:07:51
User entered 'Day 4'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-13T17:03:27', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '682076f5-8406-40cd-95a8-9c5e37e267dd' User entered 'None (1)'	System	14 Sep 2020 00:04:04
	System	14 Sep 2020 00:04:04

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:24:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-13T17:03:29', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '682076f5-8406-40cd-95a8-9c5e37e267dd' User entered 'No (N)'	System	14 Sep 2020 00:04:04
	System	14 Sep 2020 00:04:04

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-13T17:03:55', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '682076f5-8406-40cd-95a8-9c5e37e267dd' User entered 'No (N)'	System	14 Sep 2020 00:04:04
	System	14 Sep 2020 00:04:04

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-13T17:03:58', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '682076f5-8406-40cd-95a8-9c5e37e267dd' User entered 'None (1)'	System	14 Sep 2020 00:04:04
	System	14 Sep 2020 00:04:04

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:24:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-13T17:04:01', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '682076f5-8406-40cd-95a8-9c5e37e267dd' User entered '13 Sep 2020 17:04'	System	14 Sep 2020 00:04:04
	System	14 Sep 2020 00:04:04



**US3732311**

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

**Form: Injection Site\_Day(4)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:24:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:24:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
Data entry locked.	System	10 Sep 2020 19:07:51
User entered 'Day 5'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-14T12:15:10', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'd2dbcd71-198c-417c-b011-e7af2395cefc'	System	14 Sep 2020 19:15:24
User entered 'None (1)'	System	14 Sep 2020 19:15:24

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:24:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-14T12:15:12', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'd2dbcd71-198c-417c-b011-e7af2395cefc' User entered 'No (N)'	System	14 Sep 2020 19:15:24
	System	14 Sep 2020 19:15:24

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-14T12:15:14', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'd2dbcd71-198c-417c-b011-e7af2395cefc' User entered 'No (N)'	System	14 Sep 2020 19:15:24
	System	14 Sep 2020 19:15:24

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-14T12:15:17', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'd2dbcd71-198c-417c-b011-e7af2395cefc' User entered 'None (1)'	System	14 Sep 2020 19:15:24
	System	14 Sep 2020 19:15:24

**US3732311**

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

**Form: Injection Site\_Day(5)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-14T12:15:19', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'd2dbcd71-198c-417c-b011-e7af2395cefc' User entered '14 Sep 2020 12:15'	System	14 Sep 2020 19:15:24
	System	14 Sep 2020 19:15:24



**US3732311**

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

**Form: Injection Site\_Day(5)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 19:07:51

**US3732311**

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

**Form: Injection Site\_Day(5)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:24:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
Data entry locked.	System	10 Sep 2020 19:07:51
User entered 'Day 6'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-15T12:26:08', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'd6fac92e-66b2-4b08-8f7c-596da4cfb727'	System	15 Sep 2020 19:26:19
User entered 'None (1)'	System	15 Sep 2020 19:26:19

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:24:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-15T12:26:10', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'd6fac92e-66b2-4b08-8f7c-596da4cfb727'	System	15 Sep 2020 19:26:19
User entered 'No (N)'	System	15 Sep 2020 19:26:19

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-15T12:26:11', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'd6fac92e-66b2-4b08-8f7c-596da4cfb727'	System	15 Sep 2020 19:26:19
User entered 'No (N)'	System	15 Sep 2020 19:26:19

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-15T12:26:13', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'd6fac92e-66b2-4b08-8f7c-596da4cfb727'	System	15 Sep 2020 19:26:19
User entered 'None (1)'	System	15 Sep 2020 19:26:19

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:24:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-15T12:26:16', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'd6fac92e-66b2-4b08-8f7c-596da4cfb727'	System	15 Sep 2020 19:26:19
User entered '15 Sep 2020 12:26'	System	15 Sep 2020 19:26:19



**US3732311**

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

**Form: Injection Site\_Day(6)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 19:07:51

**US3732311**

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

**Form: Injection Site\_Day(6)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:24:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
Data entry locked.	System	10 Sep 2020 19:07:51
User entered 'Day 7'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-16T12:33:32', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '8b06b3e4-51b1-4d24-8a48-9e8c200d61be' User entered 'None (1)'	System	16 Sep 2020 19:33:41
	System	16 Sep 2020 19:33:41

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:24:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-16T12:33:33', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '8b06b3e4-51b1-4d24-8a48-9e8c200d61be' User entered 'No (N)'	System	16 Sep 2020 19:33:41
	System	16 Sep 2020 19:33:41

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-16T12:33:35', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '8b06b3e4-51b1-4d24-8a48-9e8c200d61be' User entered 'No (N)'	System	16 Sep 2020 19:33:41
	System	16 Sep 2020 19:33:41

US3732311

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:24:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-16T12:33:36', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '8b06b3e4-51b1-4d24-8a48-9e8c200d61be' User entered 'None (1)'	System	16 Sep 2020 19:33:41
	System	16 Sep 2020 19:33:41

**US3732311**

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

**Form: Injection Site\_Day(7)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-16T12:33:38', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '8b06b3e4-51b1-4d24-8a48-9e8c200d61be' User entered '16 Sep 2020 12:33'	System	16 Sep 2020 19:33:41
	System	16 Sep 2020 19:33:41



**US3732311**

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

**Form: Injection Site\_Day(7)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 19:07:51

**US3732311**

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

**Form: Injection Site\_Day(7)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:24:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
Data entry locked.	System	10 Sep 2020 19:07:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:24:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-10T12:35:09', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '4b24cee6-e311-4f3f-bc08-fac6c7840084' User entered 'None (0)'	System	10 Sep 2020 19:35:37
	System	10 Sep 2020 19:35:37

**US3732311**

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

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:24:11**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-10T12:35:13', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '4b24cee6-e311-4f3f-bc08-fac6c7840084' User entered 'None (0)'	System	10 Sep 2020 19:35:37
	System	10 Sep 2020 19:35:37

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:24:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-10T12:35:16', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '4b24cee6-e311-4f3f-bc08-fac6c7840084' User entered 'None (0)'	System	10 Sep 2020 19:35:37
	System	10 Sep 2020 19:35:37

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:24:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-10T12:35:18', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '4b24cee6-e311-4f3f-bc08-fac6c7840084' User entered 'None (0)'	System	10 Sep 2020 19:35:37
	System	10 Sep 2020 19:35:37

**US3732311**

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

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:24:11**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-10T12:35:21', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '4b24cee6-e311-4f3f-bc08-fac6c7840084' User entered 'None (0)'	System	10 Sep 2020 19:35:37
	System	10 Sep 2020 19:35:37



US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:24:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-10T12:35:24', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '4b24cee6-e311-4f3f-bc08-fac6c7840084' User entered 'None (0)'	System	10 Sep 2020 19:35:37
	System	10 Sep 2020 19:35:37

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-10T12:35:29', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '4b24cee6-e311-4f3f-bc08-fac6c7840084' User entered 'No (N)'	System	10 Sep 2020 19:35:37
	System	10 Sep 2020 19:35:37

**US3732311**

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

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-10T12:35:32', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '4b24cee6-e311-4f3f-bc08-fac6c7840084' User entered '10 Sep 2020 12:35'	System	10 Sep 2020 19:35:37
	System	10 Sep 2020 19:35:37

**US3732311**

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

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '10 Sep 2020 12:20'	System	10 Sep 2020 19:07:51

**US3732311**

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

**Form: General\_Day(1/1)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '10 Sep 2020 14:50'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:24:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
Data entry locked.	System	10 Sep 2020 19:07:51
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:24:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-10T18:39:27', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '6a186ec8-e2f9-4abb-ab44-92ded32e54ea' User entered 'None (0)'	System	11 Sep 2020 01:39:46
	System	11 Sep 2020 01:39:46

**US3732311**

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

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:24:11**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-10T18:39:29', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '6a186ec8-e2f9-4abb-ab44-92ded32e54ea' User entered 'None (0)'	System	11 Sep 2020 01:39:46
	System	11 Sep 2020 01:39:46



US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:24:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-10T18:39:32', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '6a186ec8-e2f9-4abb-ab44-92ded32e54ea' User entered 'None (0)'	System	11 Sep 2020 01:39:46
	System	11 Sep 2020 01:39:46

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:24:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-10T18:39:33', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '6a186ec8-e2f9-4abb-ab44-92ded32e54ea' User entered 'None (0)'	System	11 Sep 2020 01:39:46
	System	11 Sep 2020 01:39:46

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:24:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-10T18:39:35', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '6a186ec8-e2f9-4abb-ab44-92ded32e54ea' User entered 'None (0)'	System	11 Sep 2020 01:39:46
	System	11 Sep 2020 01:39:46

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:24:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-10T18:39:36', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '6a186ec8-e2f9-4abb-ab44-92ded32e54ea' User entered 'None (0)'	System	11 Sep 2020 01:39:46
	System	11 Sep 2020 01:39:46

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-10T18:39:41', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '6a186ec8-e2f9-4abb-ab44-92ded32e54ea' User entered 'No (N)'	System	11 Sep 2020 01:39:46
	System	11 Sep 2020 01:39:46

**US3732311**

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

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-10T18:39:45', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '6a186ec8-e2f9-4abb-ab44-92ded32e54ea' User entered '10 Sep 2020 18:39'	System	11 Sep 2020 01:39:46
	System	11 Sep 2020 01:39:46

**US3732311**

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

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '10 Sep 2020 15:45'	System	10 Sep 2020 19:07:51

**US3732311**

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

**Form: General\_Day(1/2)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 19:07:51



US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:24:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
Data entry locked.	System	10 Sep 2020 19:07:51
User entered 'Day 2'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:24:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-11T12:47:08', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'd8295881-a527-4c82-9ea9-014a4716973e' User entered 'None (0)'	System	11 Sep 2020 19:47:43
	System	11 Sep 2020 19:47:43

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:24:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-11T12:47:11', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'd8295881-a527-4c82-9ea9-014a4716973e' User entered 'No interference with activity (1)'	System	11 Sep 2020 19:47:43
	System	11 Sep 2020 19:47:43

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:24:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-11T12:47:17', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'd8295881-a527-4c82-9ea9-014a4716973e' User entered 'No interference with activity (1)'	System	11 Sep 2020 19:47:43
	System	11 Sep 2020 19:47:43

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:24:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-11T12:47:22', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'd8295881-a527-4c82-9ea9-014a4716973e' User entered 'No interference with activity (1)'	System	11 Sep 2020 19:47:43
	System	11 Sep 2020 19:47:43

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:24:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-11T12:47:24', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'd8295881-a527-4c82-9ea9-014a4716973e' User entered 'None (0)'	System	11 Sep 2020 19:47:43
	System	11 Sep 2020 19:47:43

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:24:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-11T12:47:26', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'd8295881-a527-4c82-9ea9-014a4716973e' User entered 'None (0)'	System	11 Sep 2020 19:47:43
	System	11 Sep 2020 19:47:43

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-11T12:47:31', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'd8295881-a527-4c82-9ea9-014a4716973e' User entered 'No (N)'	System	11 Sep 2020 19:47:43
	System	11 Sep 2020 19:47:43



US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:24:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-11T12:47:39', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'd8295881-a527-4c82-9ea9-014a4716973e' User entered '11 Sep 2020 12:47'	System	11 Sep 2020 19:47:43
	System	11 Sep 2020 19:47:43

**US3732311**

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

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 19:07:51

**US3732311**

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

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:24:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
Data entry locked.	System	10 Sep 2020 19:07:51
User entered 'Day 3'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:24:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-12T13:39:10', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'd20c3f10-3eb3-404f-8123-334264ea43ff' User entered 'None (0)'	System	12 Sep 2020 20:39:28
	System	12 Sep 2020 20:39:28

**US3732311**

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

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:24:11**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-12T13:39:13', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'd20c3f10-3eb3-404f-8123-334264ea43ff' User entered 'None (0)'	System	12 Sep 2020 20:39:28
	System	12 Sep 2020 20:39:28

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:24:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-12T13:39:14', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'd20c3f10-3eb3-404f-8123-334264ea43ff' User entered 'None (0)'	System	12 Sep 2020 20:39:28
	System	12 Sep 2020 20:39:28

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:24:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-12T13:39:16', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'd20c3f10-3eb3-404f-8123-334264ea43ff' User entered 'None (0)'	System	12 Sep 2020 20:39:28
	System	12 Sep 2020 20:39:28



**US3732311**

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

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:24:11**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-12T13:39:18', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'd20c3f10-3eb3-404f-8123-334264ea43ff' User entered 'None (0)'	System	12 Sep 2020 20:39:28
	System	12 Sep 2020 20:39:28

**US3732311**

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

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:24:11**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-12T13:39:19', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'd20c3f10-3eb3-404f-8123-334264ea43ff' User entered 'None (0)'	System	12 Sep 2020 20:39:28
	System	12 Sep 2020 20:39:28

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-12T13:39:21', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'd20c3f10-3eb3-404f-8123-334264ea43ff' User entered 'No (N)'	System	12 Sep 2020 20:39:28
	System	12 Sep 2020 20:39:28

**US3732311**

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

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-12T13:39:26', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'd20c3f10-3eb3-404f-8123-334264ea43ff' User entered '12 Sep 2020 13:39'	System	12 Sep 2020 20:39:28
	System	12 Sep 2020 20:39:28

**US3732311**

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

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 19:07:51

**US3732311**

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

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:24:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
Data entry locked.	System	10 Sep 2020 19:07:51
User entered 'Day 4'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:24:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-13T17:04:04', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '5fbab104-3df5-4173-8d71-a25ab33860d4' User entered 'None (0)'	System	14 Sep 2020 00:04:17
	System	14 Sep 2020 00:04:17



US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:24:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-13T17:04:05', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '5fbab104-3df5-4173-8d71-a25ab33860d4' User entered 'None (0)'	System	14 Sep 2020 00:04:17
	System	14 Sep 2020 00:04:17

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:24:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-13T17:04:07', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '5fbab104-3df5-4173-8d71-a25ab33860d4' User entered 'None (0)'	System	14 Sep 2020 00:04:17
	System	14 Sep 2020 00:04:17

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:24:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-13T17:04:08', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '5fbab104-3df5-4173-8d71-a25ab33860d4' User entered 'None (0)'	System	14 Sep 2020 00:04:17
	System	14 Sep 2020 00:04:17

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:24:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-13T17:04:09', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '5fbab104-3df5-4173-8d71-a25ab33860d4' User entered 'None (0)'	System	14 Sep 2020 00:04:17
	System	14 Sep 2020 00:04:17

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:24:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-13T17:04:11', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '5fbab104-3df5-4173-8d71-a25ab33860d4' User entered 'None (0)'	System	14 Sep 2020 00:04:17
	System	14 Sep 2020 00:04:17

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-13T17:04:13', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '5fbab104-3df5-4173-8d71-a25ab33860d4' User entered 'No (N)'	System	14 Sep 2020 00:04:17
	System	14 Sep 2020 00:04:17

**US3732311**

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

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-13T17:04:15', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '5fbab104-3df5-4173-8d71-a25ab33860d4' User entered '13 Sep 2020 17:04'	System	14 Sep 2020 00:04:17
	System	14 Sep 2020 00:04:17

**US3732311**

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

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 19:07:51



**US3732311**

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

**Form: General\_Day(4)**

**Generated On: 12 Aug 2021 13:24:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 19:07:51

**US3732311**

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

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

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
Data entry locked.	System	10 Sep 2020 19:07:51
User entered 'Day 5'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:24:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-14T12:16:35', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '82e76718-3f5d-4e1a-9c7d-e361d3b4eabe' User entered 'None (0)'	System	14 Sep 2020 19:17:08
	System	14 Sep 2020 19:17:08

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:24:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-14T12:16:39', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '82e76718-3f5d-4e1a-9c7d-e361d3b4eabe' User entered 'None (0)'	System	14 Sep 2020 19:17:08
	System	14 Sep 2020 19:17:08

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:24:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-14T12:16:40', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '82e76718-3f5d-4e1a-9c7d-e361d3b4eabe' User entered 'None (0)'	System	14 Sep 2020 19:17:08
	System	14 Sep 2020 19:17:08

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:24:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-14T12:16:41', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '82e76718-3f5d-4e1a-9c7d-e361d3b4eabe' User entered 'None (0)'	System	14 Sep 2020 19:17:08
	System	14 Sep 2020 19:17:08

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:24:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-14T12:16:43', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '82e76718-3f5d-4e1a-9c7d-e361d3b4eabe' User entered 'None (0)'	System	14 Sep 2020 19:17:08
	System	14 Sep 2020 19:17:08

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:24:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-14T12:16:44', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '82e76718-3f5d-4e1a-9c7d-e361d3b4eabe' User entered 'None (0)'	System	14 Sep 2020 19:17:08
	System	14 Sep 2020 19:17:08



US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-14T12:16:49', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '82e76718-3f5d-4e1a-9c7d-e361d3b4eabe' User entered 'No (N)'	System	14 Sep 2020 19:17:08
	System	14 Sep 2020 19:17:08

**US3732311**

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

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

**Generated On: 12 Aug 2021 13:24:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-14T12:16:53', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '82e76718-3f5d-4e1a-9c7d-e361d3b4eabe' User entered '14 Sep 2020 12:16'	System	14 Sep 2020 19:17:08
	System	14 Sep 2020 19:17:08

**US3732311**

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

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

**Generated On: 12 Aug 2021 13:24:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 19:07:51

**US3732311**

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

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

**Generated On: 12 Aug 2021 13:24:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:24:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
Data entry locked.	System	10 Sep 2020 19:07:51
User entered 'Day 6'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:24:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-15T12:25:52', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '88df6f08-c01a-47b1-abc2-c389e442fb0d' User entered 'None (0)'	System	15 Sep 2020 19:26:08
	System	15 Sep 2020 19:26:08

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:24:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-15T12:25:54', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '88df6f08-c01a-47b1-abc2-c389e442fb0d' User entered 'None (0)'	System	15 Sep 2020 19:26:08
	System	15 Sep 2020 19:26:08

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:24:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-15T12:25:56', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '88df6f08-c01a-47b1-abc2-c389e442fb0d' User entered 'None (0)'	System	15 Sep 2020 19:26:08
	System	15 Sep 2020 19:26:08



US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:24:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-15T12:25:57', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '88df6f08-c01a-47b1-abc2-c389e442fb0d' User entered 'None (0)'	System	15 Sep 2020 19:26:08
	System	15 Sep 2020 19:26:08

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:24:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-15T12:25:59', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '88df6f08-c01a-47b1-abc2-c389e442fb0d' User entered 'None (0)'	System	15 Sep 2020 19:26:08
	System	15 Sep 2020 19:26:08

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:24:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-15T12:26:00', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '88df6f08-c01a-47b1-abc2-c389e442fb0d' User entered 'None (0)'	System	15 Sep 2020 19:26:08
	System	15 Sep 2020 19:26:08

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-15T12:26:01', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '88df6f08-c01a-47b1-abc2-c389e442fb0d' User entered 'No (N)'	System	15 Sep 2020 19:26:08
	System	15 Sep 2020 19:26:08

**US3732311**

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

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

**Generated On: 12 Aug 2021 13:24:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-15T12:26:05', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '88df6f08-c01a-47b1-abc2-c389e442fb0d' User entered '15 Sep 2020 12:26'	System	15 Sep 2020 19:26:08
	System	15 Sep 2020 19:26:08

**US3732311**

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

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

**Generated On: 12 Aug 2021 13:24:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 19:07:51

**US3732311**

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

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

**Generated On: 12 Aug 2021 13:24:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 19:07:51

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:24:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
Data entry locked.	System	10 Sep 2020 19:07:51
User entered 'Day 7'	System	10 Sep 2020 19:07:51



**US3732311**

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

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

**Generated On: 12 Aug 2021 13:24:11**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-16T12:33:40', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '80dd45af-f7d0-47b3-bb92-43c84677632a' User entered 'None (0)'	System	16 Sep 2020 19:33:58
	System	16 Sep 2020 19:33:58

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:24:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-16T12:33:42', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '80dd45af-f7d0-47b3-bb92-43c84677632a' User entered 'None (0)'	System	16 Sep 2020 19:33:58
	System	16 Sep 2020 19:33:58

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:24:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-16T12:33:43', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '80dd45af-f7d0-47b3-bb92-43c84677632a' User entered 'None (0)'	System	16 Sep 2020 19:33:58
	System	16 Sep 2020 19:33:58

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:24:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-16T12:33:44', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '80dd45af-f7d0-47b3-bb92-43c84677632a' User entered 'None (0)'	System	16 Sep 2020 19:33:58
	System	16 Sep 2020 19:33:58

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:24:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-16T12:33:45', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '80dd45af-f7d0-47b3-bb92-43c84677632a' User entered 'None (0)'	System	16 Sep 2020 19:33:58
	System	16 Sep 2020 19:33:58

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:24:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-16T12:33:46', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '80dd45af-f7d0-47b3-bb92-43c84677632a' User entered 'None (0)'	System	16 Sep 2020 19:33:58
	System	16 Sep 2020 19:33:58

US3732311

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-16T12:33:49', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '80dd45af-f7d0-47b3-bb92-43c84677632a' User entered 'No (N)'	System	16 Sep 2020 19:33:58
	System	16 Sep 2020 19:33:58

**US3732311**

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

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

**Generated On: 12 Aug 2021 13:24:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-09-16T12:33:55', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '80dd45af-f7d0-47b3-bb92-43c84677632a' User entered '16 Sep 2020 12:33'	System	16 Sep 2020 19:33:58
	System	16 Sep 2020 19:33:58



**US3732311**

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

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

**Generated On: 12 Aug 2021 13:24:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 19:07:51

**US3732311**

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

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

**Generated On: 12 Aug 2021 13:24:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:25:27
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 19:07:51

US3732311

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 21:11:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:01:39
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	17 Sep 2020 18:35:21
	(b) (4)	

US3732311

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 21:11:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:01:39
User entered '17 Sep 2020'	Lauren Arnett (b) (4)	17 Sep 2020 18:35:21
	(b) (4)	

US3732311

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 21:11:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:01:39
User entered 'Contact Made (CONTACT MADE)'	Lauren Arnett (b) (4)	17 Sep 2020 18:35:21

**US3732311**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:24:11**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 21:11:59
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:01:39
User entered empty.	Lauren Arnett (b) (4)	17 Sep 2020 18:35:21

US3732311

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:40:52
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:02:15
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	17 Sep 2020 18:35:26
	(b) (4)	

**US3732311**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:24:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:40:52
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered 'l'	System	17 Sep 2020 18:35:26



US3732311

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:36:57
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:02:34
User entered 'Yes (Y)'	Sylvia Lindholm (b) (4)	24 Sep 2020 17:34:18

US3732311

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:36:57
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:02:34
User entered '24 Sep 2020'	Sylvia Lindholm (b) (4)	24 Sep 2020 17:34:18

US3732311

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:36:57
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:02:34
User entered 'Contact Made (CONTACT MADE)'	Sylvia Lindholm (b) (4)	24 Sep 2020 17:34:18

US3732311

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:36:57
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:02:34
User entered empty.	Sylvia Lindholm (b) (4)	24 Sep 2020 17:34:18

US3732311

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:01
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:02:44
User entered 'Yes (Y)'	Sylvia Lindholm (b) (4)	24 Sep 2020 17:34:24

**US3732311**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:24:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:01
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered 'l'	System	24 Sep 2020 17:34:24

**US3732311**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:24:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:15
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:02:53
User entered 'Yes (Y)'		01 Oct 2020 19:28:32

US3732311

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:15
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:02:53
User entered '01 Oct 2020'		01 Oct 2020 19:28:32



US3732311

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:15
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:02:53
User entered 'Contact Made (CONTACT MADE)'		01 Oct 2020 19:28:32

US3732311

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:15
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:02:53
User entered empty.		01 Oct 2020 19:28:32

US3732311

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:21
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:03:08
User entered 'Yes (Y)'		01 Oct 2020 19:29:00

**US3732311**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:24:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:21
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered 'l'	System	01 Oct 2020 19:29:00

**US3732311**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:24:11**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:04:24
User entered 'Yes (Y)'	Amara Yilmaz (b) (4)	14 Oct 2020 18:04:57

US3732311

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:24:11

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:04:24
User entered '08 Oct 2020'	Amara Yilmaz (b) (4)	14 Oct 2020 18:04:57
	(b) (4)	

US3732311

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:04:24
User entered 'Clinic (Clinic)'	Amara Yilmaz (b) (4)	14 Oct 2020 18:04:57
	(b) (4)	

**US3732311**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:24:11**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered 'VISIT2'	System	14 Oct 2020 18:04:57



US3732311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:32
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User accepted default value 'Pre-Dose (PREDOSE)'	Amara Yilmaz (b) (4) (b) (4)	14 Oct 2020 18:09:33

US3732311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:32
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:05:15
User entered 'Yes (Y)'	Amara Yilmaz (b) (4)	14 Oct 2020 18:09:33
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:11

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:32
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:05:15
User entered '08 Oct 2020'	Amara Yilmaz (b) (4)	14 Oct 2020 18:09:33
	(b) (4)	

US3732311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:32
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:05:15
User entered '10:15'	Amara Yilmaz (b) (4)	14 Oct 2020 18:09:33
	(b) (4)	

**US3732311**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 12 Aug 2021 13:24:11**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:32
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered '08 Oct 2020 10:15'	System	14 Oct 2020 18:09:33

US3732311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:32
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:05:15
User entered '98.7' F	Amara Yilmaz (b) (4)	14 Oct 2020 18:09:33
	(b) (4)	

US3732311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:32
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:05:15
User entered 'Oral (Oral)'	Amara Yilmaz (b) (4)	14 Oct 2020 18:09:33
	(b) (4)	

US3732311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:32
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:05:15
User entered empty.	Amara Yilmaz (b) (4)	14 Oct 2020 18:09:33
	(b) (4)	



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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:32
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:05:15
User entered '88'	Amara Yilmaz (b) (4)	14 Oct 2020 18:09:33
	(b) (4)	

US3732311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:32
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered 'bpm'	System	14 Oct 2020 18:09:33

US3732311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:32
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:05:15
User entered '16'	Amara Yilmaz (b) (4)	14 Oct 2020 18:09:33
	(b) (4)	

US3732311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:32
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered 'breaths/min'	System	14 Oct 2020 18:09:33

US3732311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:32
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:05:15
User entered '123'	Amara Yilmaz (b) (4)	14 Oct 2020 18:09:33
	(b) (4)	

US3732311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:32
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered 'mmHg'	System	14 Oct 2020 18:09:33

US3732311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:32
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:05:15
User entered '79'	Amara Yilmaz (b) (4)	14 Oct 2020 18:09:33
	(b) (4)	

US3732311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:24:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:32
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered 'mmHg'	System	14 Oct 2020 18:09:33



US3732311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:32
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User accepted default value 'Post-Dose (POSTDOSE)'	Amara Yilmaz (b) (4) (b) (4)	14 Oct 2020 18:09:33

US3732311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:32
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:35:32
User entered 'No (N)'	Amara Yilmaz (b) (4)	14 Oct 2020 18:09:33
	(b) (4)	

US3732311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:32
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:35:32
User entered empty.	Amara Yilmaz (b) (4)	14 Oct 2020 18:09:33
	(b) (4)	

**US3732311**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:24:11**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:32
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:35:32
User entered empty.	Amara Yilmaz (b) (4)	14 Oct 2020 18:09:33
	(b) (4)	

**US3732311**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:24:11**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:32
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered empty.	System	14 Oct 2020 18:09:33

US3732311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:32
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:35:32
User entered empty.	Amara Yilmaz (b) (4)	14 Oct 2020 18:09:33
	(b) (4)	

US3732311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:32
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:35:32
User entered empty.	Amara Yilmaz (b) (4)	14 Oct 2020 18:09:33
	(b) (4)	

US3732311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:32
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:35:32
User entered empty.	Amara Yilmaz (b) (4)	14 Oct 2020 18:09:33
	(b) (4)	



US3732311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:32
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:35:32
User entered empty.	Amara Yilmaz (b) (4)	14 Oct 2020 18:09:33
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:32
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered empty.	System	14 Oct 2020 18:09:33

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:32
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:35:32
User entered empty.	Amara Yilmaz (b) (4)	14 Oct 2020 18:09:33
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:32
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered empty.	System	14 Oct 2020 18:09:33

US3732311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:32
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:35:32
User entered empty.	Amara Yilmaz (b) (4)	14 Oct 2020 18:09:33
	(b) (4)	

**US3732311**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 12 Aug 2021 13:24:11**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:32
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered empty.	System	14 Oct 2020 18:09:33

US3732311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:32
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:35:32
User entered empty.	Amara Yilmaz (b) (4)	14 Oct 2020 18:09:33
	(b) (4)	

US3732311

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:24:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:32
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered empty.	System	14 Oct 2020 18:09:33



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Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:24:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:37
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:04:54
User entered 'Yes (Y)'	Amara Yilmaz (b) (4)	14 Oct 2020 18:05:18
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:24:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:37
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:04:54
User entered '08 Oct 2020'	Amara Yilmaz (b) (4)	14 Oct 2020 18:05:18
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:24:11

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:05:36
User entered 'Yes (Y)'	Amara Yilmaz (b) (4)	14 Oct 2020 18:06:26
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:24:11

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:05:36
User entered '08 Oct 2020'	Amara Yilmaz (b) (4)	14 Oct 2020 18:06:26
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:24:11

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:05:36
User entered 'Urine (URINE)'	Amara Yilmaz (b) (4)	14 Oct 2020 18:06:26
	(b) (4)	

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**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:24:11**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:05:36
User entered 'Negative (NEGATIVE)'	Amara Yilmaz (b) (4)	14 Oct 2020 18:06:26
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:24:11

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:05:36
User entered 'No (N)'	Amara Yilmaz (b) (4)	14 Oct 2020 18:06:26
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:24:11

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:05:36
User entered empty.	Amara Yilmaz (b) (4)	14 Oct 2020 18:06:26
	(b) (4)	



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Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:24:11

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:05:36
User entered empty.	Amara Yilmaz (b) (4)	14 Oct 2020 18:06:26
	(b) (4)	

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**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 12 Aug 2021 13:24:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:41
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered empty.	System	14 Oct 2020 18:06:26

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:24:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:45
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:05:48
User entered 'No (N)'	Amara Yilmaz (b) (4)	14 Oct 2020 18:08:57
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:24:11

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:45
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:05:48
User closed query 'Per CDM: Reason noted. However, No corresponding AE that caused the Investigational Product to be withdrawn is recorded in the AE CRF. Please review and reconcile. ' (Site from DM).		01 Dec 2020 09:11:15
Query 'Per CDM: Reason noted. However, No corresponding AE that caused the Investigational Product to be withdrawn is recorded in the AE CRF. Please review and reconcile. ' answered with 'AE #1 already documented ' (Site from DM).	Lauren Arnett (b) (4) (b) (4)	30 Oct 2020 21:53:31
User opened query 'Per CDM: Reason noted. However, No corresponding AE that caused the Investigational Product to be withdrawn is recorded in the AE CRF. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 08:24:04
User entered 'Participant declined due to Adverse Event (ADVERSE EVENT)'	Amara Yilmaz (b) (4) (b) (4)	14 Oct 2020 18:08:57

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:24:11

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)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:45
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:05:48
User entered empty.	Amara Yilmaz (b) (4)	14 Oct 2020 18:08:57
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:24:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:45
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered empty.	System	14 Oct 2020 18:08:57

US3732311

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:24:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:45
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:05:48
User entered empty.	Amara Yilmaz (b) (4)	14 Oct 2020 18:08:57
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:24:11

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:45
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:05:48
User entered empty.	Amara Yilmaz (b) (4)	14 Oct 2020 18:08:57
	(b) (4)	



**US3732311**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 12 Aug 2021 13:24:11**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:45
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered empty.	System	14 Oct 2020 18:08:57

US3732311

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:24:11

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:45
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:05:48
User entered empty.	Amara Yilmaz (b) (4)	14 Oct 2020 18:08:57
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:24:11

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.		09 Apr 2021 14:37:45
Data hard locked.		29 Mar 2021 09:11:31
DataPoint Verified.		02 Dec 2020 23:05:48
User entered empty.	System	14 Oct 2020 18:08:57

US3732311

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:24:11

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:45
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered empty.	System	14 Oct 2020 18:08:57

US3732311

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:24:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:49
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:05:29
User entered 'Yes (Y)'	Amara Yilmaz (b) (4)	14 Oct 2020 18:07:39
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:24:11

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:49
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:05:29
User entered '08 Oct 2020'	Amara Yilmaz (b) (4)	14 Oct 2020 18:07:39
	(b) (4)	

US3732311

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:24:11

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:49
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:05:29
User entered '10:40'	Amara Yilmaz (b) (4)	14 Oct 2020 18:07:39
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:24:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:49
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered '08 Oct 2020 10:40'	System	14 Oct 2020 18:07:39



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Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:24:11

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:53
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:05:23
User entered '08 Oct 2020'	Amara Yilmaz (b) (4)	14 Oct 2020 18:08:16

US3732311

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:24:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:53
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Amara Yilmaz (b) (4) (b) (4)	14 Oct 2020 18:08:16

US3732311

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:24:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:53
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:05:23
User entered 'Yes (Y)'	Amara Yilmaz (b) (4)	14 Oct 2020 18:08:16
	(b) (4)	

US3732311

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:24:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:53
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:05:23
User entered '10:20'	Amara Yilmaz (b) (4)	14 Oct 2020 18:08:16
	(b) (4)	

**US3732311**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:24:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:53
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered '08 Oct 2020 10:20'	System	14 Oct 2020 18:08:16

US3732311

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:24:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:53
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Amara Yilmaz (b) (4) (b) (4)	14 Oct 2020 18:08:16

US3732311

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:24:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:53
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:05:23
User entered 'No (N)'	Amara Yilmaz (b) (4)	14 Oct 2020 18:08:16
	(b) (4)	

US3732311

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:24:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:53
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:05:23
User entered empty.	Amara Yilmaz (b) (4)	14 Oct 2020 18:08:16
	(b) (4)	



**US3732311**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 13:24:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:53
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered empty.	System	14 Oct 2020 18:08:16

US3732311

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:57
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:05:53
User entered 'Yes (Y)'	Amara Yilmaz (b) (4)	14 Oct 2020 18:08:21
	(b) (4)	

**US3732311**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:24:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:37:57
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered 'l'	System	14 Oct 2020 18:08:21

**US3732311**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:24:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:38:13
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:11:28
User entered 'Yes (Y)'	Linda Vega (b) (4)	15 Oct 2020 21:26:10

US3732311

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:38:13
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:11:28
User entered '15 Oct 2020'	Linda Vega (b) (4)	15 Oct 2020 21:26:10
	(b) (4)	

US3732311

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:38:13
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:11:28
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4)	15 Oct 2020 21:26:10

US3732311

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:38:13
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:11:28
User entered empty.	Linda Vega (b) (4)	15 Oct 2020 21:26:10
	(b) (4)	

US3732311

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:38:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:11:44
User entered 'Yes (Y)'	Linda Vega (b) (4)	15 Oct 2020 17:14:14
	(b) (4)	



**US3732311**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:24:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:38:18
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered 'l'	System	15 Oct 2020 17:14:14

US3732311

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:38:24
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:11:53
User entered 'Yes (Y)'	Linda Vega (b) (4)	22 Oct 2020 23:35:27
	(b) (4)	

US3732311

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:38:24
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:11:53
User entered '22 Oct 2020'	Linda Vega (b) (4)	22 Oct 2020 23:35:27
	(b) (4)	

US3732311

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:38:24
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:11:53
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4)	22 Oct 2020 23:35:27

US3732311

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:38:24
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:11:53
User entered empty.	Linda Vega (b) (4)	22 Oct 2020 23:35:27
	(b) (4)	

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Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:38:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:12:00
User entered 'Yes (Y)'	Linda Vega (b) (4)	22 Oct 2020 23:35:31
	(b) (4)	

**US3732311**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:24:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:38:28
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered 'l'	System	22 Oct 2020 23:35:31

**US3732311**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:24:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:38:38
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:12:07
User entered 'Yes (Y)'	Linda Vega (b) (4)	29 Oct 2020 21:49:23
	(b) (4)	



US3732311

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:38:38
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:12:07
User entered '29 Oct 2020'	Linda Vega (b) (4)	29 Oct 2020 21:49:23
	(b) (4)	

US3732311

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:38:38
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:12:07
User entered 'Contact Made (CONTACT MADE)'	Linda Vega (b) (4)	29 Oct 2020 21:49:23

US3732311

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:38:38
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:12:07
User entered empty.	Linda Vega (b) (4) (b) (4)	29 Oct 2020 21:49:23

US3732311

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:38:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:12:12
User entered 'Yes (Y)'	Linda Vega (b) (4)	29 Oct 2020 21:49:27
	(b) (4)	

**US3732311**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:24:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:38:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered 'l'	System	29 Oct 2020 21:49:27

**US3732311**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:24:11**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:39:47
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:12:19
User entered 'Yes (Y)'	Amara Yilmaz (b) (4)	09 Nov 2020 21:48:23
	(b) (4)	

**US3732311**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:24:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:39:47
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:12:19
User entered '05 Nov 2020'	Amara Yilmaz (b) (4)	09 Nov 2020 21:48:23
	(b) (4)	

US3732311

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:24:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:39:47
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:12:19
User entered 'Clinic (Clinic)'	Amara Yilmaz (b) (4)	09 Nov 2020 21:48:23
	(b) (4)	



**US3732311**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:24:11**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:39:47
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered 'VISIT3'	System	09 Nov 2020 21:48:23

US3732311

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:39:35
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:12:54
User entered 'Yes (Y)'	Amara Yilmaz (b) (4)	09 Nov 2020 22:07:41
	(b) (4)	

US3732311

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:11

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:39:35
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:12:54
User entered '05 Nov 2020'	Amara Yilmaz (b) (4)	09 Nov 2020 22:07:41
	(b) (4)	

**US3732311**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:24:11**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:39:35
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:12:54
User entered '09:05'	Amara Yilmaz (b) (4)	09 Nov 2020 22:07:41
	(b) (4)	

**US3732311**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:24:11**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:39:35
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered '05 Nov 2020 09:05'	System	09 Nov 2020 22:07:41

US3732311

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:39:35
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:12:54
User entered '98.1' F	Amara Yilmaz (b) (4)	09 Nov 2020 22:07:41
	(b) (4)	

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Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:39:35
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:12:54
User entered 'Oral (Oral)'	Amara Yilmaz (b) (4)	09 Nov 2020 22:07:41
	(b) (4)	

US3732311

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:39:35
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:12:54
User entered empty.	Amara Yilmaz (b) (4)	09 Nov 2020 22:07:41
	(b) (4)	



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Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:39:35
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:12:54
User entered '100'	Amara Yilmaz (b) (4)	09 Nov 2020 22:07:41
	(b) (4)	

**US3732311**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:24:11**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:39:35
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered 'bpm'	System	09 Nov 2020 22:07:41

US3732311

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:39:35
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:12:54
User entered '16'	Amara Yilmaz (b) (4)	09 Nov 2020 22:07:41
	(b) (4)	

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Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:39:35
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered 'breaths/min'	System	09 Nov 2020 22:07:41

US3732311

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:11

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:39:35
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:12:54
User entered '115'	Amara Yilmaz (b) (4)	09 Nov 2020 22:07:41
	(b) (4)	

US3732311

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:39:35
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered 'mmHg'	System	09 Nov 2020 22:07:41

US3732311

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:39:35
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:12:54
User entered '74'	Amara Yilmaz (b) (4)	09 Nov 2020 22:07:41
	(b) (4)	

**US3732311**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:24:11**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:39:35
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered 'mmHg'	System	09 Nov 2020 22:07:41



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Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:39:35
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31

US3732311

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:11

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:39:35
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31

US3732311

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:24:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:39:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:12:37
User entered 'Yes (Y)'	Amara Yilmaz (b) (4)	09 Nov 2020 22:07:04
	(b) (4)	

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Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:24:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:39:42
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:12:37
User entered '05 Nov 2020'	Amara Yilmaz (b) (4)	09 Nov 2020 22:07:04
	(b) (4)	

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Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:24:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:39:26
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:13:01
User entered 'Yes (Y)'	Amara Yilmaz (b) (4)	09 Nov 2020 22:08:01
	(b) (4)	

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Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:24:11

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:39:26
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:13:01
User entered '05 Nov 2020'	Amara Yilmaz (b) (4)	09 Nov 2020 22:08:01
	(b) (4)	

US3732311

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:24:11

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:39:26
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:13:01
User entered '09:20'	Amara Yilmaz (b) (4)	09 Nov 2020 22:08:01
	(b) (4)	

**US3732311**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:24:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:39:26
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered '05 Nov 2020 09:20'	System	09 Nov 2020 22:08:01



US3732311

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:39:20
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:13:10
User entered 'Yes (Y)'	Amara Yilmaz (b) (4)	09 Nov 2020 22:08:06
	(b) (4)	

**US3732311**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:24:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:39
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:39:20
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered 'l'	System	09 Nov 2020 22:08:06

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27
Data entry locked.	System	10 Sep 2020 19:07:51
User entered 'Day 64'	System	10 Sep 2020 19:07:51

US3732311

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

[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 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Have you been exposed to someone with 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 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Please 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 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[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 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Please 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 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

US3732311

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

[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 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Please 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 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27
Data entry locked.	System	10 Sep 2020 19:07:51
User entered '10 Nov 2020 00:01'	System	10 Sep 2020 19:07:51

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27
Data entry locked.	System	10 Sep 2020 19:07:51
User entered '14 Nov 2020 23:59'	System	10 Sep 2020 19:07:51

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27
Data entry locked.	System	10 Sep 2020 19:07:51
User entered 'Day 71'	System	10 Sep 2020 19:07:51

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[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 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27



US3732311

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

Have you been exposed to someone with 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 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Please 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 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

US3732311

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

[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 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Please 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 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

US3732311

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:24:11

[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 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Please 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 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27
Data entry locked.	System	10 Sep 2020 19:07:51
User entered '17 Nov 2020 00:01'	System	10 Sep 2020 19:07:51

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:16:27
Data entry locked.	System	10 Sep 2020 19:07:51
User entered '21 Nov 2020 23:59'	System	10 Sep 2020 19:07:51

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 07:16:27



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 07:16:27



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[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 (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-12-27T19:18:53', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '8cafcb18-e48b-4b55-b2c5-17c7245f73bb' User entered 'No (N)'	System	28 Dec 2020 03:19:05
	System	28 Dec 2020 03:19:05

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

Have you been exposed to someone with 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 (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-12-27T19:18:58', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '8cafc18-e48b-4b55-b2c5-17c7245f73bb'	System	28 Dec 2020 03:19:05
User entered 'No (N)'	System	28 Dec 2020 03:19:05

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (97E436BA-B380-4ACE-8421-35B8E12453D8)', Time: '2020-12-27T19:19:01', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '8cafcb18-e48b-4b55-b2c5-17c7245f73bb' User entered '27 Dec 2020 19:19:01'	System	28 Dec 2020 03:19:05

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 07:16:27



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[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 (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-01-13T15:47:07', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '70e3b2fb-08a0-4e58-8349-b7e8219dd069'	System	13 Jan 2021 23:47:15
User entered 'No (N)'	System	13 Jan 2021 23:47:15

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Have you been exposed to someone with 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 (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-01-13T15:47:09', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '70e3b2fb-08a0-4e58-8349-b7e8219dd069'	System	13 Jan 2021 23:47:15
User entered 'No (N)'	System	13 Jan 2021 23:47:15

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-01-13T15:47:14', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '70e3b2fb-08a0-4e58-8349-b7e8219dd069' User entered '13 Jan 2021 15:47:14'	System	13 Jan 2021 23:47:15
	System	13 Jan 2021 23:47:15

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 07:16:27



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[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 (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-01-16T07:18:58', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'e0544da5-d54c-4c06-9f9c-1ee7ceb35fca' User entered 'No (N)'	System	16 Jan 2021 15:19:12
	System	16 Jan 2021 15:19:12

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Have you been exposed to someone with 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 (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-01-16T07:19:05', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'e0544da5-d54c-4c06-9f9c-1ee7ceb35fca' User entered 'No (N)'	System	16 Jan 2021 15:19:12

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-01-16T07:19:10', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'e0544da5-d54c-4c06-9f9c-1ee7ceb35fca' User entered '16 Jan 2021 07:19:10'	System	16 Jan 2021 15:19:12
	System	16 Jan 2021 15:19:12

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[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 (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-01-23T07:26:42', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '46cdba5d-eac7-4e37-9d52-faf87df08a4f' User entered 'No (N)'	System	23 Jan 2021 15:26:51



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Have you been exposed to someone with 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 (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-01-23T07:26:45', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '46cdba5d-eac7-4e37-9d52-faf87df08a4f' User entered 'No (N)'	System	23 Jan 2021 15:26:51

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-01-23T07:26:48', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '46cdba5d-eac7-4e37-9d52-faf87df08a4f' User entered '23 Jan 2021 07:26:48'	System	23 Jan 2021 15:26:51
	System	23 Jan 2021 15:26:51

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[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 (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-01-30T08:42:46', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'e6900c29-be92-4a5d-8c6b-4ef6bb770eac' User entered 'No (N)'	System	06 Feb 2021 15:29:30
	System	06 Feb 2021 15:29:30

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Have you been exposed to someone with 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 (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-01-30T08:42:50', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'e6900c29-be92-4a5d-8c6b-4ef6bb770eac' User entered 'No (N)'	System	06 Feb 2021 15:29:30
	System	06 Feb 2021 15:29:30

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-01-30T08:42:56', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'e6900c29-be92-4a5d-8c6b-4ef6bb770eac' User entered '30 Jan 2021 08:42:56'	System	06 Feb 2021 15:29:30
	System	06 Feb 2021 15:29:30



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[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 (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-02-06T07:30:10', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '378f1ff6-b943-4af9-be99-08ccbd746a2e' User entered 'No (N)'	System	06 Feb 2021 15:30:21
	System	06 Feb 2021 15:30:21

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

Have you been exposed to someone with 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 (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-02-06T07:30:12', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '378f1ff6-b943-4af9-be99-08ccbd746a2e' User entered 'No (N)'	System	06 Feb 2021 15:30:21

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-02-06T07:30:17', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '378f1ff6-b943-4af9-be99-08ccbd746a2e' User entered '06 Feb 2021 07:30:17'	System	06 Feb 2021 15:30:21
	System	06 Feb 2021 15:30:21

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 07:16:27



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[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 (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-02-13T07:57:08', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '1a945e94-d4bb-496a-b5ff-5e72287e013d' User entered 'No (N)'	System	13 Feb 2021 15:57:19
	System	13 Feb 2021 15:57:19

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Have you been exposed to someone with 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 (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-02-13T07:57:11', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '1a945e94-d4bb-496a-b5ff-5e72287e013d' User entered 'No (N)'	System	13 Feb 2021 15:57:19
	System	13 Feb 2021 15:57:19

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-02-13T07:57:17', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '1a945e94-d4bb-496a-b5ff-5e72287e013d' User entered '13 Feb 2021 07:57:17'	System	13 Feb 2021 15:57:19
	System	13 Feb 2021 15:57:19

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[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 (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-02-20T07:09:36', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'eb9c738d-c259-4cda-9158-efaa9813488d' User entered 'No (N)'	System	20 Feb 2021 15:09:50
	System	20 Feb 2021 15:09:50



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

Have you been exposed to someone with 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 (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-02-20T07:09:43', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'eb9c738d-c259-4cda-9158-efaa9813488d' User entered 'No (N)'	System	20 Feb 2021 15:09:50
	System	20 Feb 2021 15:09:50

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-02-20T07:09:47', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'eb9c738d-c259-4cda-9158-efaa9813488d' User entered '20 Feb 2021 07:09:47'	System	20 Feb 2021 15:09:50
	System	20 Feb 2021 15:09:50

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[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 (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-02-27T08:14:44-08:00', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '7bc7f332-5ed5-411a-a234-b6f69cab574e' User entered 'No (N)'	System	27 Feb 2021 16:14:50
	System	27 Feb 2021 16:14:50

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

Have you been exposed to someone with 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 (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-02-27T08:14:46-08:00', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '7bc7f332-5ed5-411a-a234-b6f69cab574e' User entered 'No (N)'	System	27 Feb 2021 16:14:50
	System	27 Feb 2021 16:14:50

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-02-27T08:14:48-08:00', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '7bc7f332-5ed5-411a-a234-b6f69cab574e' User entered '27 Feb 2021 16:14:48'	System	27 Feb 2021 16:14:50
	System	27 Feb 2021 16:14:50



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[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 (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-03-06T08:07:03-08:00', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'b0f93c1f-a641-408e-aa94-f8626313b22b'	System	06 Mar 2021 16:07:13
User entered 'No (N)'	System	06 Mar 2021 16:07:13

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

Have you been exposed to someone with 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 (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-03-06T08:07:06-08:00', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'b0f93c1f-a641-408e-aa94-f8626313b22b'	System	06 Mar 2021 16:07:13
User entered 'No (N)'	System	06 Mar 2021 16:07:13

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-03-06T08:07:08-08:00', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'b0f93c1f-a641-408e-aa94-f8626313b22b'	System	06 Mar 2021 16:07:13
User entered '06 Mar 2021 08:07:08'	System	06 Mar 2021 16:07:13

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 07:16:27



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[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 (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-03-13T08:08:30-08:00', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '642e0451-59c1-4eaa-a487-f74f078cde90'	System	13 Mar 2021 16:08:39
User entered 'No (N)'	System	13 Mar 2021 16:08:39

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

Have you been exposed to someone with 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 (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-03-13T08:08:32-08:00', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '642e0451-59c1-4eaa-a487-f74f078cde90'	System	13 Mar 2021 16:08:39
User entered 'No (N)'	System	13 Mar 2021 16:08:39

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-03-13T08:08:37-08:00', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '642e0451-59c1-4eaa-a487-f74f078cde90' User entered '13 Mar 2021 08:08:37'	System	13 Mar 2021 16:08:39
	System	13 Mar 2021 16:08:39

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[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 (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-03-20T07:59:22-07:00', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '7587f62d-e172-4589-92d4-9d6f0a5d33dd' User entered 'No (N)'	System	20 Mar 2021 14:59:32
	System	20 Mar 2021 14:59:32



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

Have you been exposed to someone with 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 (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-03-20T07:59:26-07:00', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '7587f62d-e172-4589-92d4-9d6f0a5d33dd' User entered 'No (N)'	System	20 Mar 2021 14:59:32

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-03-20T07:59:28-07:00', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '7587f62d-e172-4589-92d4-9d6f0a5d33dd' User entered '20 Mar 2021 07:59:28'	System	20 Mar 2021 14:59:32
	System	20 Mar 2021 14:59:32

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[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 (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-03-30T17:59:22-07:00', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'b7bf6f94-0083-4d5e-a880-7c7b2e13458c'	System	31 Mar 2021 00:59:34
User entered 'No (N)'	System	31 Mar 2021 00:59:34

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

Have you been exposed to someone with 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 (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-03-30T17:59:25-07:00', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'b7bf6f94-0083-4d5e-a880-7c7b2e13458c'	System	31 Mar 2021 00:59:34
User entered 'No (N)'	System	31 Mar 2021 00:59:34

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-03-30T17:59:28-07:00', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'b7bf6f94-0083-4d5e-a880-7c7b2e13458c'	System	31 Mar 2021 00:59:34
User entered '30 Mar 2021 17:59:28'	System	31 Mar 2021 00:59:34



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[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 (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-04-05T12:06:19-07:00', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'e1993e49-ffd1-4bb4-b79a-8a159eff975f' User entered 'No (N)'	System	05 Apr 2021 19:07:26
	System	05 Apr 2021 19:07:26

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

Have you been exposed to someone with 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 (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-04-05T12:06:24-07:00', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'e1993e49-ffd1-4bb4-b79a-8a159eff975f' User entered 'No (N)'	System	05 Apr 2021 19:07:26

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-04-05T12:06:26-07:00', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'e1993e49-ffd1-4bb4-b79a-8a159eff975f' User entered '05 Apr 2021 12:06:26'	System	05 Apr 2021 19:07:26
	System	05 Apr 2021 19:07:26

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 07:16:27



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[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 (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-04-10T07:41:02-07:00', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'c4a52a3f-8ee1-496b-87d8-37fd3140fa22'	System	10 Apr 2021 14:41:10
User entered 'No (N)'	System	10 Apr 2021 14:41:10

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

Have you been exposed to someone with 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 (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-04-10T07:41:06-07:00', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'c4a52a3f-8ee1-496b-87d8-37fd3140fa22'	System	10 Apr 2021 14:41:10
User entered 'No (N)'	System	10 Apr 2021 14:41:10

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-04-10T07:41:08-07:00', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'c4a52a3f-8ee1-496b-87d8-37fd3140fa22'	System	10 Apr 2021 14:41:10
User entered '10 Apr 2021 07:41:08'	System	10 Apr 2021 14:41:10

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[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 (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-04-18T13:58:43-07:00', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'e6297863-20bc-4785-b4ea-2b3eca9d7909'	System	18 Apr 2021 20:58:50
User entered 'No (N)'	System	18 Apr 2021 20:58:50



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

Have you been exposed to someone with 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 (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-04-18T13:58:45-07:00', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'e6297863-20bc-4785-b4ea-2b3eca9d7909'	System	18 Apr 2021 20:58:50
User entered 'No (N)'	System	18 Apr 2021 20:58:50

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-04-18T13:58:47-07:00', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'e6297863-20bc-4785-b4ea-2b3eca9d7909'	System	18 Apr 2021 20:58:50
User entered '18 Apr 2021 13:58:47'	System	18 Apr 2021 20:58:50

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[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 (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-04-24T08:23:55-07:00', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '030bf984-582a-4b0d-9db8-038ec04492cb' User entered 'No (N)'	System	24 Apr 2021 15:24:04
	System	24 Apr 2021 15:24:04

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

Have you been exposed to someone with 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 (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-04-24T08:23:57-07:00', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '030bf984-582a-4b0d-9db8-038ec04492cb' User entered 'No (N)'	System	24 Apr 2021 15:24:04

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-04-24T08:24:00-07:00', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: '030bf984-582a-4b0d-9db8-038ec04492cb' User entered '24 Apr 2021 08:24:00'	System	24 Apr 2021 15:24:04
	System	24 Apr 2021 15:24:04



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[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 (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-05-01T07:06:27-07:00', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'b9234cc9-e660-4259-a889-91415da904b4'	System	01 May 2021 14:06:34
User entered 'No (N)'	System	01 May 2021 14:06:34

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

Have you been exposed to someone with 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 (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-05-01T07:06:29-07:00', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'b9234cc9-e660-4259-a889-91415da904b4'	System	01 May 2021 14:06:34
User entered 'No (N)'	System	01 May 2021 14:06:34

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-05-01T07:06:31-07:00', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'b9234cc9-e660-4259-a889-91415da904b4'	System	01 May 2021 14:06:34
User entered '01 May 2021 07:06:31'	System	01 May 2021 14:06:34

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 07:16:27



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 07:16:27



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 07:16:27



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 07:16:27



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 07:16:27



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 07:16:27



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 07:16:27



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 07:16:27



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 07:16:27



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 07:16:27



**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 07:16:27

**US3732311**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 07:16:27



**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 07:16:27



**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 07:16:27



**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 07:16:27



**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 07:16:27



**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 07:16:27



**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 07:16:27



**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 07:16:27



**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 07:16:27



**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 07:16:27



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 07:16:27



**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 07:16:27



**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 07:16:27



**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 07:16:27



**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 07:16:27



**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 07:16:27



**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 07:16:27



**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 07:16:27



**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 07:16:27



**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 07:16:27



**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 07:16:27

**US3732311**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:24:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:16:27
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 07:16:27



US3732311

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 12 Aug 2021 13:24:11**

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 04:36:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-02-27T08:14:55-08:00', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'e4a7a245-9660-4f29-8f6a-54fd07d3567e' User entered 'No (N)'	System	27 Feb 2021 16:15:04
	System	27 Feb 2021 16:15:04

**US3732311**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 12 Aug 2021 13:24:11**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 04:36:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6C29C790-82B1-4D5E-BEE1-7C9D67A24E49)', Time: '2021-02-27T08:14:59-08:00', User OID: 'PatientReportedOutcome (US3732311)', ODM File OID: 'e4a7a245-9660-4f29-8f6a-54fd07d3567e' User entered '27 Feb 2021 16:14:59'	System	27 Feb 2021 16:15:04
	System	27 Feb 2021 16:15:04

US3732311

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:40:16
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:16:28
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
User entered 'Yes (Y)'	(b) (4)	
	Sylvia Lindholm (b) (4)	04 Dec 2020 21:44:38

US3732311

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:40:16
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:16:28
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
User entered '04 Dec 2020' reason for change: Data Entry Error	(b) (4) Sylvia Lindholm (b) (4)	04 Dec 2020 21:44:43
User entered '4 Dec 2020'	Sylvia Lindholm (b) (4)	04 Dec 2020 21:44:38

US3732311

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:40:16
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:16:28
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sylvia Lindholm (b) (4)	04 Dec 2020 21:44:38

US3732311

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:40:16
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:16:28
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
User entered empty.	(b) (4) Sylvia Lindholm (b) (4)	04 Dec 2020 21:44:38

US3732311

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:40:20
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:16:59
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
User entered 'Yes (Y)'	(b) (4) Sylvia Lindholm (b) (4)	04 Dec 2020 21:44:48

**US3732311**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:24:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:14:38
Data hard unlocked.	(b) (4), (b) (6)	09 Apr 2021 14:40:20
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 09:11:31
User entered 'l'	System	04 Dec 2020 21:44:48



**US3732311**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:24:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:43:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:18:28
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
User entered 'Yes (Y)'	(b) (4) Sylvia Lindholm (b) (4)	07 Jan 2021 01:45:07

**US3732311**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:24:11**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:43:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:18:28
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
User entered '6 Jan 2021'	(b) (4) Sylvia Lindholm (b) (4)	07 Jan 2021 01:45:07

US3732311

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:43:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:18:28
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sylvia Lindholm (b) (4)	07 Jan 2021 01:45:07

**US3732311**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:24:11**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:43:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:18:28
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
User entered empty.	(b) (4) Sylvia Lindholm (b) (4)	07 Jan 2021 01:45:07

US3732311

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:43:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:19:07
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
User entered 'Yes (Y)'	(b) (4) Sylvia Lindholm (b) (4)	07 Jan 2021 01:45:12

**US3732311**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:24:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:43:28
User entered '1'	System	07 Jan 2021 01:45:12

**US3732311**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:24:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:43:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:26:11
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
User entered 'Yes (Y)'	(b) (4) Sylvia Lindholm (b) (4)	06 Feb 2021 20:17:40

**US3732311**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:24:11**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:43:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:26:11
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
User entered '6 Feb 2021'	(b) (4) Sylvia Lindholm (b) (4)	06 Feb 2021 20:17:40



US3732311

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:43:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:26:11
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sylvia Lindholm (b) (4)	06 Feb 2021 20:17:40

**US3732311**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:24:11**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:43:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:26:11
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
User entered empty.	(b) (4) Sylvia Lindholm (b) (4)	06 Feb 2021 20:17:40

US3732311

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:43:28
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:26:53
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
User entered 'Yes (Y)'	(b) (4) Sylvia Lindholm (b) (4)	06 Feb 2021 20:17:47

**US3732311**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:24:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 07:43:28
User entered 'I'	System	06 Feb 2021 20:17:47

**US3732311**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:24:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:23
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:28:08
User entered 'Yes (Y)'	Sylvia Lindholm (b) (4)	09 Mar 2021 16:57:45

**US3732311**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:24:11**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:23
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:28:08
User entered '09 Mar 2021'	Sylvia Lindholm (b) (4)	09 Mar 2021 16:57:45

US3732311

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:23
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:28:08
User entered 'Contact Made (CONTACT MADE)'	Sylvia Lindholm (b) (4)	09 Mar 2021 16:57:45

US3732311

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:24:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:23
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:28:08
User entered empty.	Sylvia Lindholm (b) (4)	09 Mar 2021 16:57:45



US3732311

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:23
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:28:27
User entered 'Yes (Y)'	Sylvia Lindholm (b) (4)	09 Mar 2021 16:57:50

**US3732311**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:24:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:53:23
User entered 'I'	System	09 Mar 2021 16:57:50

**US3732311**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:24:11**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
	(b) (4)	
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	06 Apr 2021 18:33:32
	(b) (4)	

**US3732311**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:24:11**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
	(b) (4)	
User entered '06 Apr 2021'	Gordon Bovee (b) (4)	06 Apr 2021 18:33:32
	(b) (4)	

US3732311

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:24:11

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
	(b) (4)	
User entered 'Clinic (Clinic)'	Gordon Bovee (b) (4)	06 Apr 2021 18:33:32
	(b) (4)	

**US3732311**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:24:11**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	06 Apr 2021 18:33:32

**US3732311**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:24:11**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
	(b) (4)	
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	06 Apr 2021 18:34:54
	(b) (4)	

US3732311

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
	(b) (4)	
User entered '06 Apr 2021'	Gordon Bovee (b) (4)	06 Apr 2021 18:34:54
	(b) (4)	



**US3732311**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:24:11**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
	(b) (4)	
User entered '10:33'	Gordon Bovee (b) (4)	06 Apr 2021 18:34:54
	(b) (4)	

**US3732311**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:24:11**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '06 Apr 2021 10:33'	System	06 Apr 2021 18:34:54

US3732311

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:11

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
	(b) (4)	
User entered '98.3' F	Gordon Bovee (b) (4)	06 Apr 2021 18:34:54
	(b) (4)	

**US3732311**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:24:11**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
	(b) (4)	
User entered 'Oral (Oral)'	Gordon Bovee (b) (4)	06 Apr 2021 18:34:54
	(b) (4)	

US3732311

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:11

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
	(b) (4)	
User entered empty.	Gordon Bovee (b) (4)	06 Apr 2021 18:34:54
	(b) (4)	

**US3732311**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:24:11**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
	(b) (4)	
User entered '94'	Gordon Bovee (b) (4)	06 Apr 2021 18:34:54
	(b) (4)	

**US3732311**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:24:11**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	06 Apr 2021 18:34:54

**US3732311**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:24:11**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
	(b) (4)	
User entered '17'	Gordon Bovee (b) (4)	06 Apr 2021 18:34:54
	(b) (4)	



US3732311

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	06 Apr 2021 18:34:54

US3732311

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
	(b) (4)	
User entered '133'	Gordon Bovee (b) (4)	06 Apr 2021 18:34:54
	(b) (4)	

US3732311

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Apr 2021 18:34:54

**US3732311**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:24:11**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
	(b) (4)	
User entered '81'	Gordon Bovee (b) (4)	06 Apr 2021 18:34:54
	(b) (4)	

US3732311

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:24:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	06 Apr 2021 18:34:54

US3732311

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:24:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
	(b) (4)	
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	06 Apr 2021 18:33:57
	(b) (4)	

**US3732311**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 12 Aug 2021 13:24:11**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
	(b) (4)	
User entered '06 Apr 2021'	Gordon Bovee (b) (4)	06 Apr 2021 18:33:57
	(b) (4)	

**US3732311**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:24:11**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
User entered 'Yes (Y)'	(b) (4) Gordon Bovee (b) (4)	06 Apr 2021 18:36:31
	(b) (4)	



US3732311

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:24:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
	(b) (4)	
User entered '06 Apr 2021'	Gordon Bovee (b) (4)	06 Apr 2021 18:36:31
	(b) (4)	

**US3732311**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:24:11**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
User entered '10:38'	(b) (4) Gordon Bovee (b) (4)	06 Apr 2021 18:36:31
	(b) (4)	

**US3732311**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:24:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '06 Apr 2021 10:38'	System	06 Apr 2021 18:36:31

US3732311

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:24:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
	(b) (4)	
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	06 Apr 2021 18:36:47
	(b) (4)	

**US3732311**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:24:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 18:36:47

**US3732311**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:24:11**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
	(b) (4)	
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	06 Apr 2021 18:39:05
	(b) (4)	

**US3732311**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:24:11**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
	(b) (4)	
User entered '06 Apr 2021'	Gordon Bovee (b) (4)	06 Apr 2021 18:39:05
	(b) (4)	

US3732311

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:24:11

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
User entered 'Clinic (Clinic)'	(b) (4) Gordon Bovee (b) (4) (b) (4)	06 Apr 2021 18:39:05



**US3732311**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:24:11**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'UNBLND_DECIDE'	System	06 Apr 2021 18:39:05

US3732311

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:24:11

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
	(b) (4)	
User entered '06 Apr 2021'	Gordon Bovee (b) (4)	06 Apr 2021 18:47:15
	(b) (4)	

**US3732311**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 12 Aug 2021 13:24:11**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
	(b) (4)	
User entered '0'	Gordon Bovee (b) (4)	06 Apr 2021 18:47:15
	(b) (4)	

US3732311

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:24:11

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
	(b) (4)	
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	06 Apr 2021 18:47:15
	(b) (4)	

**US3732311**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 12 Aug 2021 13:24:11**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) Gordon Bovee (b) (4)	06 Apr 2021 18:47:15

US3732311

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:24:11

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
	(b) (4)	
User entered '06 Apr 2021'	Gordon Bovee (b) (4)	06 Apr 2021 18:47:15
	(b) (4)	

US3732311

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:24:11

[Participant randomization assignment](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Gordon Bovee (b) (4)	06 Apr 2021 18:47:15

US3732311

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:24:11

[Actual Dose 1](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Gordon Bovee (b) (4)	06 Apr 2021 18:47:15



US3732311

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:24:11

[Actual Dose 2](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
	(b) (4)	
User entered 'Not Administered (NA)'	Gordon Bovee (b) (4)	06 Apr 2021 18:47:15
	(b) (4)	

US3732311

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:24:11

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
	(b) (4)	
User entered 'No (N)'	Gordon Bovee (b) (4)	06 Apr 2021 18:47:15
	(b) (4)	

**US3732311**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 12 Aug 2021 13:24:11**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 18:47:15

**US3732311**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 12 Aug 2021 13:24:11**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 18:47:15

US3732311

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:24:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
	(b) (4)	
User entered 'Yes (Y)'	Gordon Bovee (b) (4)	06 Apr 2021 18:47:50
	(b) (4)	

US3732311

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:24:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
	(b) (4)	
User entered '06 Apr 2021'	Gordon Bovee (b) (4)	06 Apr 2021 18:47:50
	(b) (4)	

**US3732311**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:24:11**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
	(b) (4)	
User entered '10:38'	Gordon Bovee (b) (4)	06 Apr 2021 18:47:50
	(b) (4)	

**US3732311**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:24:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '06 Apr 2021 10:38'	System	06 Apr 2021 18:47:50



**US3732311**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 12 Aug 2021 13:24:11**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
User entered 'Yes (Y)'	(b) (4) Gordon Bovee (b) (4)	06 Apr 2021 18:48:10

**US3732311**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 12 Aug 2021 13:24:11**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
	(b) (4)	
User entered '06 Apr 2021'	Gordon Bovee (b) (4)	06 Apr 2021 18:48:10
	(b) (4)	

**US3732311**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 12 Aug 2021 13:24:11**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
	(b) (4)	
User entered '10:35'	Gordon Bovee (b) (4)	06 Apr 2021 18:48:10
	(b) (4)	

**US3732311**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 12 Aug 2021 13:24:11**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '06 Apr 2021 10:35'	System	06 Apr 2021 18:48:10

**US3732311**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 12 Aug 2021 13:24:11**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:32:05
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:14:15
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	24 Sep 2020 23:10:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:24:11

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site lymphadenopathy, LLT: Injection site lymphadenopathy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Mar 2021 15:33:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Mar 2021 15:33:16
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	26 Feb 2021 01:41:25
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Lymphadenopathy axillary - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Jan 2021 16:20:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Jan 2021 16:20:58
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:15:58
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site lymphadenopathy, LLT: Injection site lymphadenopathy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 00:29:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 00:29:35
User closed query 'Per CDM: To help clarify the clinical significance of the event of LEFT AXILLARY LYMPHADENOPATHY and possible association with the administration of investigational product and/or study procedure, if this is related to the site of administration, please update the Adverse Event to 'INJECTION SITE LEFT AXILLARY LYMPHADENOPATHY' ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 05:45:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:24:11

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per CDM: To help clarify the clinical significance of the event of LEFT AXILLARY LYMPHADENOPATHY and possible association with the administration of investigational product and/or study procedure, if this is related to the site of administration, please update the Adverse Event to 'INJECTION SITE LEFT AXILLARY LYMPHADENOPATHY' ' answered with 'updated' (Site from DM). Data point term sent to Coder Coding entries removed.	Lauren Arnett (b) (4) (b) (4)	30 Oct 2020 21:49:15
	System	30 Oct 2020 21:49:01
	Lauren Arnett (b) (4) (b) (4)	30 Oct 2020 21:48:56
User entered 'LEFT AXILLARY LYMPHADENOPATHY at injection site' reason for change: Per Query Resolution	Lauren Arnett (b) (4) (b) (4)	30 Oct 2020 21:48:56
Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, this AE started after the 7-day post vaccination period for collecting solicited events. Please review and update response to 'Was this a Solicited Adverse Reaction?' as appropriate. Otherwise, clarify.' canceled (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 23:25:08
User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, this AE started after the 7-day post vaccination period for collecting solicited events. Please review and update response to 'Was this a Solicited Adverse Reaction?' as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 19:48:11
User opened query 'Per CDM: To help clarify the clinical significance of the event of LEFT AXILLARY LYMPHADENOPATHY and possible association with the administration of investigational product and/or study procedure, if this is related to the site of administration, please update the Adverse Event to 'INJECTION SITE LEFT AXILLARY LYMPHADENOPATHY' (Site from DM).	(b) (4), (b) (6)	11 Oct 2020 11:18:21
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Lymphadenopathy axillary - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 23:20:46

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:24:11

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	24 Sep 2020 23:20:46
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	24 Sep 2020 23:19:08
User entered 'left axillary lymphadenopathy'	Lauren Arnett (b) (4)	24 Sep 2020 23:18:19
	(b) (4)	



**US3732311**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:24:11**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:15:58
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	24 Sep 2020 23:18:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:24:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4)	02 Dec 2020 23:15:58
User closed query 'Per DM CLR - RQ: Site's response noted. However, solicited reactions are only reported as AE if it meets AE reporting criteria per Protocol section 8.3.4. This AE started after Day 7 (onwards) post vaccination, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 14:38:07
Query 'Per DM CLR - RQ: Site's response noted. However, solicited reactions are only reported as AE if it meets AE reporting criteria per Protocol section 8.3.4. This AE started after Day 7 (onwards) post vaccination, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to No. Else, provide clarification.' answered with 'data has been corrected, due to AE being reported on Day 8 after IP this is not considered a solicited adverse reaction ' (Site from DM).	Amara Yilmaz (b) (4)	11 Nov 2020 20:38:35
User entered 'No (N)' reason for change: New Information	(b) (4)	11 Nov 2020 20:37:52
User opened query 'Per DM CLR - RQ: Site's response noted. However, solicited reactions are only reported as AE if it meets AE reporting criteria per Protocol section 8.3.4. This AE started after Day 7 (onwards) post vaccination, review if this is considered as unsolicited event per protocol section 8.3.4. If yes, update this field to No. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 05:45:07
User closed query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, this AE started after the 7-day post vaccination period for collecting solicited events. Please review and update response to 'Was this a Solicited Adverse Reaction?' as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 05:45:07

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:24:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, this AE started after the 7-day post vaccination period for collecting solicited events. Please review and update response to 'Was this a Solicited Adverse Reaction?' as appropriate. Otherwise, clarify. ' answered with 'swelling and pain at injection site are protocol defined AR's, which is why Solicited adverse reaction is selected as yes. Please advise' (Site from DM).	Lauren Arnett (b) (4) (b) (4)	30 Oct 2020 21:50:40
User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, this AE started after the 7-day post vaccination period for collecting solicited events. Please review and update response to 'Was this a Solicited Adverse Reaction?' as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6) (b) (4)	23 Oct 2020 23:25:13
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	24 Sep 2020 23:18:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:24:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:15:58
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	24 Sep 2020 23:18:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:24:11

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:15:58
User entered '18 Sep 2020'	Lauren Arnett (b) (4)	24 Sep 2020 23:18:19

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:24:11**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 23:15:58
User entered empty.	Lauren Arnett (b) (4)	24 Sep 2020 23:18:19
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:24:11**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 23:18:19

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:24:11**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 23:15:58
User entered 'No (N)' reason for change: New Information	Amara Yilmaz (b) (4)	09 Nov 2020 21:47:10
	(b) (4)	
User entered 'Yes (Y)'	Lauren Arnett (b) (4)	24 Sep 2020 23:18:19
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:24:11**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:15:58
User entered '22 Oct 2020' reason for change: New Information	Amara Yilmaz (b) (4) (b) (4)	09 Nov 2020 21:47:10
User entered empty.	Lauren Arnett (b) (4) (b) (4)	24 Sep 2020 23:18:19

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:24:11**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 23:15:58
User entered empty.	Lauren Arnett (b) (4)	24 Sep 2020 23:18:19
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:24:11**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 23:18:19

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:24:11**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:15:58
User entered 'Grade 1/Mild (Grade 1/Mild)'	Lauren Arnett (b) (4) (b) (4)	24 Sep 2020 23:18:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:24:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:15:58
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	24 Sep 2020 23:18:19

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:24:11**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:15:58
User entered '0'	Lauren Arnett (b) (4) (b) (4)	24 Sep 2020 23:18:19

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:24:11**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:15:58
User entered '0'	Lauren Arnett (b) (4) (b) (4)	24 Sep 2020 23:18:19

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:24:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:15:58
User entered '0'	Lauren Arnett (b) (4) (b) (4)	24 Sep 2020 23:18:19



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:24:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:15:58
User entered empty.	Lauren Arnett (b) (4) (b) (4)	24 Sep 2020 23:18:19

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:24:11**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:15:58
User entered empty.	Lauren Arnett (b) (4) (b) (4)	24 Sep 2020 23:18:19

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:24:11**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:15:58
User entered empty.	Lauren Arnett (b) (4) (b) (4)	24 Sep 2020 23:18:19

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:24:11**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:15:58
User entered empty.	Lauren Arnett (b) (4) (b) (4)	24 Sep 2020 23:18:19

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:24:11**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:15:58
User entered '0'	Lauren Arnett (b) (4) (b) (4)	24 Sep 2020 23:18:19

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:24:11**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 23:15:58
User entered '0'	Lauren Arnett (b) (4)	24 Sep 2020 23:18:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:24:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:15:58
User entered '0'	Lauren Arnett (b) (4) (b) (4)	24 Sep 2020 23:18:19

**US3732311**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:24:11**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4)	02 Dec 2020 23:15:58
User entered 'Related (RELATED)'	(b) (4), (b) (6)	02 Dec 2020 23:15:58
	Lauren Arnett (b) (4)	24 Sep 2020 23:18:19
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:24:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 23:15:58
User entered 'Not Related (NOT RELATED)'	Amara Yilmaz (b) (4)	09 Nov 2020 21:47:10
reason for change: New Information	(b) (4)	
User entered 'Related (RELATED)'	Lauren Arnett (b) (4)	24 Sep 2020 23:18:19
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:24:11**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:15:58
User entered 'None (NONE)'	Lauren Arnett (b) (4) (b) (4)	24 Sep 2020 23:18:19

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:24:11**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4)	02 Dec 2020 23:15:58
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 22:18:55
User entered '1'	Lauren Arnett (b) (4)	24 Sep 2020 23:18:19
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:24:11**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 23:15:58
User entered '1' reason for change: Data Entry Error		24 Nov 2020 22:18:55
User entered '0'	Lauren Arnett (b) (4)	24 Sep 2020 23:18:19
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:24:11**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 23:15:58
User entered '0'	Lauren Arnett (b) (4)	24 Sep 2020 23:18:19
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:24:11**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 23:15:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Amara Yilmaz (b) (4)	09 Nov 2020 21:47:10
Data Entry Error	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Lauren Arnett (b) (4)	24 Sep 2020 23:18:19
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:24:11**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:15:58
User entered empty.	Lauren Arnett (b) (4) (b) (4)	24 Sep 2020 23:18:19

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:24:11**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 23:15:58
User entered empty.	Lauren Arnett (b) (4)	24 Sep 2020 23:18:19
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:24:11**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Sep 2020 23:18:19

**US3732311**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:24:11**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Sep 2020 23:18:19

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:24:11**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:24:11

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:20:51
User coded data point as SOC: Product issues, HLGT: Device issues, HLT: Device issues NEC, PT: Device dislocation, LLT: Migration of implant - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 20:36:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 20:36:31
Data point term sent to Coder	System	14 Oct 2020 18:13:36
User entered 'displaced left breast silicone implant'	Amara Yilmaz (b) (4) (b) (4)	14 Oct 2020 18:12:55

**US3732311**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:24:11**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:20:51
User entered 'Yes (Y)'	Amara Yilmaz (b) (4) (b) (4)	14 Oct 2020 18:12:55

**US3732311**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:24:11**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:20:51
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	14 Oct 2020 18:12:55

**US3732311**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:24:11**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:20:51
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	14 Oct 2020 18:12:55

**US3732311**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:24:11**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:20:51
User entered '29 Sep 2020'	Amara Yilmaz (b) (4)	14 Oct 2020 18:12:55
	(b) (4)	



**US3732311**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:24:11**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:20:51
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	14 Oct 2020 18:12:55

**US3732311**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:24:11**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:15
User entered empty.	System	14 Oct 2020 18:12:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:24:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:30:05
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Feb 2021 07:33:52
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'data has been corrected ' (Site from DM).	Amara Yilmaz (b) (4) (b) (4)	08 Feb 2021 23:19:52
DataPoint Un-verified.	Amara Yilmaz (b) (4) (b) (4)	08 Feb 2021 23:19:33
User entered 'No (N)' reason for change: Data Entry Error	Amara Yilmaz (b) (4) (b) (4)	08 Feb 2021 23:19:33
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 23:21:02
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:20:51
User entered 'Yes (Y)'	Amara Yilmaz (b) (4) (b) (4)	14 Oct 2020 18:12:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:24:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:30:10
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Un-verified.	(b) (4) Amara Yilmaz (b) (4)	08 Feb 2021 23:19:33
User entered '05 Oct 2020' reason for change: Data Entry Error	(b) (4) Amara Yilmaz (b) (4)	08 Feb 2021 23:19:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:20:51
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	14 Oct 2020 18:12:55

**US3732311**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:24:11**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:20:51
User entered empty.	Amara Yilmaz (b) (4)	14 Oct 2020 18:12:55

**US3732311**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:24:11**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:15
User entered empty.	System	14 Oct 2020 18:12:55

**US3732311**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:24:11**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:20:51
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Amara Yilmaz (b) (4) (b) (4)	14 Oct 2020 18:12:55

**US3732311**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:24:11**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:20:51
User entered 'No (N)'	Amara Yilmaz (b) (4)	14 Oct 2020 18:12:55



**US3732311**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:24:11**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:20:51
User entered '0'	Amara Yilmaz (b) (4)	14 Oct 2020 18:12:55

**US3732311**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:24:11**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:20:51
User entered '0'	Amara Yilmaz (b) (4)	14 Oct 2020 18:12:55

**US3732311**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:24:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:20:51
User entered '0'	Amara Yilmaz (b) (4)	14 Oct 2020 18:12:55
	(b) (4)	

**US3732311**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:24:11**

**Hospital Admission Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:20:51
User entered empty.	Amara Yilmaz (b) (4)	14 Oct 2020 18:12:55

**US3732311**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:24:11**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:20:51
User entered empty.	Amara Yilmaz (b) (4)	14 Oct 2020 18:12:55

**US3732311**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:24:11**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:20:51
User entered empty.	Amara Yilmaz (b) (4)	14 Oct 2020 18:12:55

**US3732311**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:24:11**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:20:51
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	14 Oct 2020 18:12:55

**US3732311**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:24:11**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:20:51
User entered '0'	Amara Yilmaz (b) (4) (b) (4)	14 Oct 2020 18:12:55



**US3732311**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:24:11**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:20:51
User entered '0'	Amara Yilmaz (b) (4) (b) (4)	14 Oct 2020 18:12:55

**US3732311**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:24:11**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:20:51
User entered '0'	Amara Yilmaz (b) (4) (b) (4)	14 Oct 2020 18:12:55

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:24:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4)	02 Dec 2020 23:20:51
User closed query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 09:47:12
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 01:24:50
Query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' answered with 'updated ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 01:24:39
User opened query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 06:52:15
User entered 'Not Applicable (NOT APPLICABLE)'	Amara Yilmaz (b) (4)	14 Oct 2020 18:12:55

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:24:11**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:20:51
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4)	24 Nov 2020 01:24:50
User entered 'Not Applicable (NOT APPLICABLE)'	Amara Yilmaz (b) (4)	14 Oct 2020 18:12:55
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:24:11**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:20:51
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error		24 Nov 2020 01:25:06
User entered 'None (NONE)'	Amara Yilmaz (b) (4) (b) (4)	14 Oct 2020 18:12:55

**US3732311**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:24:11**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:20:51
User entered '0' reason for change: New Information	Lauren Arnett (b) (4)	02 Dec 2020 17:24:44
User entered '1'	Amara Yilmaz (b) (4)	14 Oct 2020 18:12:55

**US3732311**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:24:11**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:20:51
User entered '0'	Amara Yilmaz (b) (4)	14 Oct 2020 18:12:55

**US3732311**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:24:11**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:20:51
User entered '1' reason for change: New Information	Lauren Arnett (b) (4)	02 Dec 2020 17:24:44
User entered '0'	Amara Yilmaz (b) (4)	14 Oct 2020 18:12:55



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:24:11

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:15
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:30:14
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Un-verified.	(b) (4) Amara Yilmaz (b) (4)	08 Feb 2021 23:19:33
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) Amara Yilmaz (b) (4)	08 Feb 2021 23:19:33
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:20:51
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Amara Yilmaz (b) (4) (b) (4)	14 Oct 2020 18:12:55

**US3732311**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:24:11**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:20:51
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	14 Oct 2020 18:12:55

**US3732311**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:24:11**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:15
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:20:51
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	14 Oct 2020 18:12:55

**US3732311**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:24:11**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:15
User entered '0'	System	14 Oct 2020 18:12:55

**US3732311**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:24:11**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:15
User entered '1'	System	14 Oct 2020 18:12:55

**US3732311**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 12 Aug 2021 13:24:11**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:57:15

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 12 Aug 2021 13:24:11**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:32:05
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:20:57
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 18:33:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:24:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 23:33:04
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 21:37:03
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 21:37:03
	(b) (4)	
Data point term sent to Coder	System	24 Nov 2020 17:23:54
Coding entries removed.	(b) (4), (b) (6)	24 Nov 2020 17:23:43
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 18:35:48
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 18:35:48
	(b) (4)	
Data point term sent to Coder	System	11 Sep 2020 18:34:26
User entered 'fish oil'	Lauren Arnett (b) (4)	11 Sep 2020 18:33:39
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:24:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review if this indication should be recorded in the MH eCRF. If yes, update MH eCRF and prophylaxis field to No. Otherwise, provide clarification or update indication (e.g. Supplement, General Health).' canceled (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 04:00:12
User opened query 'Per DM CLR: Please review if this indication should be recorded in the MH eCRF. If yes, update MH eCRF and prophylaxis field to No. Otherwise, provide clarification or update indication (e.g. Supplement, General Health).' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 04:00:05
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:33:04
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	24 Nov 2020 17:23:43
User entered 'No (N)'	Lauren Arnett (b) (4)	11 Sep 2020 18:33:39
	(b) (4)	

US3732311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:24:11

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if this indication should be recorded in the MH eCRF. If yes, update MH eCRF and prophylaxis field to No. Otherwise, provide clarification or update indication (e.g. Supplement, General Health).' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 07:02:45
Query 'Per DM CLR: Please review if this indication should be recorded in the MH eCRF. If yes, update MH eCRF and prophylaxis field to No. Otherwise, provide clarification or update indication (e.g. Supplement, General Health).' answered with 'data is correct, vitamins and supplements were instructed to be reported as prophylaxis' (Site from DM).	Amara Yilmaz (b) (4)	10 Mar 2021 17:22:41
User opened query 'Per DM CLR: Please review if this indication should be recorded in the MH eCRF. If yes, update MH eCRF and prophylaxis field to No. Otherwise, provide clarification or update indication (e.g. Supplement, General Health).' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 03:59:53
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, please confirm whether there is an existing actual condition of Malnutrition requiring this medication. If yes, please ensure that there is a corresponding MH/AE condition recorded that matches this medication and review if the prophylaxis field should be changed to NO, as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 11:26:52
Query 'Per DM CLR: Prophylaxis is marked as YES. However, please confirm whether there is an existing actual condition of Malnutrition requiring this medication. If yes, please ensure that there is a corresponding MH/AE condition recorded that matches this medication and review if the prophylaxis field should be changed to NO, as appropriate. Otherwise, provide clarification.' answered with 'No existing condition of malnutrition reported; this medication is taken as prophylaxis.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 22:44:27

US3732311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:24:11

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, please confirm whether there is an existing actual condition of Malnutrition requiring this medication. If yes, please ensure that there is a corresponding MH/AE condition recorded that matches this medication and review if the prophylaxis field should be changed to NO, as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 02:18:32
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:33:04
User entered 'malnutrition' reason for change: New Information	(b) (4), (b) (6)	24 Nov 2020 17:23:43
User entered 'nutritional supplement'	Lauren Arnett (b) (4)	11 Sep 2020 18:33:39
	(b) (4)	

US3732311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:24:11

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:30:38
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 09:48:48
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'data has been updated ' (Site from DM).	Amara Yilmaz (b) (4)	08 Feb 2021 23:21:24
DataPoint Un-verified.	Amara Yilmaz (b) (4)	08 Feb 2021 23:21:00
User entered '2000' reason for change: Data Entry Error	Amara Yilmaz (b) (4)	08 Feb 2021 23:21:00
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 02:18:39
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:33:04
User entered '1'	Lauren Arnett (b) (4)	11 Sep 2020 18:33:39

US3732311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:24:11

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:30:40
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
User entered 'ug (ug)' reason for change: Data Entry Error	Amara Yilmaz (b) (4)	08 Feb 2021 23:21:09
DataPoint Un-verified.	Amara Yilmaz (b) (4)	08 Feb 2021 23:21:00
User entered 'mg (mg)' reason for change: Data Entry Error	Amara Yilmaz (b) (4)	08 Feb 2021 23:21:00
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:33:04
User entered 'tablet (TABLET)'	Lauren Arnett (b) (4)	11 Sep 2020 18:33:39

US3732311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:24:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:33:04
User entered empty.	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 18:33:39

US3732311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:24:11**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:33:04
User entered 'once daily (QD)'	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 18:33:39

US3732311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:24:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:33:04
User entered empty.	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 18:33:39



US3732311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:24:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 23:33:04
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4)	11 Sep 2020 18:33:39
	(b) (4)	

US3732311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:24:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:33:04
User entered empty.	Lauren Arnett (b) (4)	11 Sep 2020 18:33:39

US3732311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:24:11**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4)	02 Dec 2020 23:33:04
User entered 'un UNK 2010'	(b) (4), (b) (6)	11 Sep 2020 18:33:39
	Lauren Arnett (b) (4)	
	(b) (4)	

**US3732311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:24:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:33:04
User entered '0'	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 18:33:39

**US3732311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:24:11**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:33:04
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 18:33:39

**US3732311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:24:11**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:33:04
User entered empty.	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 18:33:39

US3732311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:24:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:33:04
User entered 'No (N)'	Lauren Arnett (b) (4)	11 Sep 2020 18:33:39

**US3732311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:24:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 18:33:39



**US3732311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:24:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 18:33:39

**US3732311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:24:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 18:33:39

US3732311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:24:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 23:33:09
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 17:57:03
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 17:57:03
	(b) (4)	
Data point term sent to Coder	System	24 Nov 2020 17:24:56
Coding entries removed.	(b) (4), (b) (6)	24 Nov 2020 17:24:26
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 18:35:47
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 18:35:47
	(b) (4)	
Data point term sent to Coder	System	11 Sep 2020 18:34:26
User entered 'multivitamin'	Lauren Arnett (b) (4)	11 Sep 2020 18:34:08
	(b) (4)	

US3732311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:24:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 23:33:09
User entered 'Yes (Y)' reason for change: New Information		24 Nov 2020 17:24:26
User entered 'No (N)'	Lauren Arnett (b) (4)	11 Sep 2020 18:34:08
	(b) (4)	

US3732311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:24:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, please confirm whether there is an existing actual condition of Vitamin Deficiency requiring this medication. If yes, please ensure that there is a corresponding MH/AE condition recorded that matches this medication and review if the prophylaxis field should be changed to NO, as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 11:27:08
Query 'Per DM CLR: Prophylaxis is marked as YES. However, please confirm whether there is an existing actual condition of Vitamin Deficiency requiring this medication. If yes, please ensure that there is a corresponding MH/AE condition recorded that matches this medication and review if the prophylaxis field should be changed to NO, as appropriate. Otherwise, provide clarification.' answered with 'No existing condition of vitamin deficiency reported; this medication is taken as prophylaxis.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 22:45:03
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, please confirm whether there is an existing actual condition of Vitamin Deficiency requiring this medication. If yes, please ensure that there is a corresponding MH/AE condition recorded that matches this medication and review if the prophylaxis field should be changed to NO, as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 02:18:52
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:33:09
User entered 'vitamin deficiency' reason for change: New Information	(b) (4), (b) (6)	24 Nov 2020 17:24:26
User entered 'nutritional supplement'	Lauren Arnett (b) (4)	11 Sep 2020 18:34:08
	(b) (4)	

US3732311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:24:11**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 23:33:09
User entered 'I'	Lauren Arnett (b) (4)	11 Sep 2020 18:34:08
	(b) (4)	

**US3732311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:24:11**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 23:33:09
User entered 'tablet (TABLET)'	Lauren Arnett (b) (4)	11 Sep 2020 18:34:08
	(b) (4)	

US3732311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:24:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:33:09
User entered empty.	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 18:34:08



**US3732311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:24:11**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:33:09
User entered 'once daily (QD)'	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 18:34:08

US3732311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:24:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:33:09
User entered empty.	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 18:34:08

US3732311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:24:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:33:09
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 18:34:08

US3732311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:24:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4)	02 Dec 2020 23:33:09
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 18:34:08
	Lauren Arnett (b) (4)	
	(b) (4)	

US3732311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:24:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:33:09
User entered 'un UNK 2010'	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 18:34:08

US3732311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:24:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4)	02 Dec 2020 23:33:09
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 18:34:08
	Lauren Arnett (b) (4)	
	(b) (4)	

**US3732311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:24:11**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:33:09
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 18:34:08

**US3732311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:24:11**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:33:09
User entered empty.	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 18:34:08



**US3732311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:24:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:33:09
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 18:34:08

**US3732311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:24:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 18:34:08

US3732311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:24:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 18:34:08

**US3732311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:24:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 18:34:08

US3732311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:24:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:33:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: QUETIAPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 18:35:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 18:35:48
Data point term sent to Coder	System	11 Sep 2020 18:35:27
User entered 'quetiapine'	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 18:34:40

US3732311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:24:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:33:13
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 18:34:40

US3732311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:24:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 23:33:13
User entered 'insomnia'	Lauren Arnett (b) (4)	11 Sep 2020 18:34:40
	(b) (4)	

**US3732311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:24:11**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:33:13
User entered '25'	Lauren Arnett (b) (4)	11 Sep 2020 18:34:40



US3732311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:24:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:33:13
User entered 'mg (mg)'	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 18:34:40

US3732311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:24:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:33:13
User entered empty.	Lauren Arnett (b) (4)	11 Sep 2020 18:34:40

US3732311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:24:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 23:33:13
User entered 'as needed (PRN)'	Lauren Arnett (b) (4)	11 Sep 2020 18:34:40
	(b) (4)	

US3732311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:24:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:33:13
User entered empty.	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 18:34:40

US3732311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:24:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:33:13
User entered 'Oral (ORAL)'	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 18:34:40

US3732311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:24:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:33:13
User entered empty.	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 18:34:40

US3732311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:24:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 23:33:13
User entered 'un UNK 2019'	Lauren Arnett (b) (4)	11 Sep 2020 18:34:40
	(b) (4)	

**US3732311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:24:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:33:13
User entered '0'	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 18:34:40



**US3732311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:24:11**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:33:13
User entered 'Yes (Y)'	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 18:34:40

US3732311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:24:11**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:33:13
User entered empty.	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 18:34:40

US3732311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:24:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:33:13
User entered 'No (N)'	Lauren Arnett (b) (4) (b) (4)	11 Sep 2020 18:34:40

**US3732311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:24:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 18:34:40

**US3732311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:24:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 18:34:40

**US3732311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:24:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Sep 2020 18:34:40

US3732311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:24:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 23:33:20
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 21:07:36
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 Nov 2020 21:07:36
Data point term sent to Coder	System	11 Nov 2020 20:47:49
User entered 'ibuprofen'	Amara Yilmaz (b) (4) (b) (4)	11 Nov 2020 20:47:12

**US3732311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:24:11**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:33:20
User entered 'No (N)'	Amara Yilmaz (b) (4) (b) (4)	11 Nov 2020 20:47:12



**US3732311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:24:11**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:33:20
User entered 'left axillary lymphadenopathy'	Amara Yilmaz (b) (4) (b) (4)	11 Nov 2020 20:47:12

US3732311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:24:11**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 23:33:20
User entered '200'	Amara Yilmaz (b) (4)	11 Nov 2020 20:47:12
	(b) (4)	

US3732311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:24:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:33:20
User entered 'mg (mg)'	Amara Yilmaz (b) (4) (b) (4)	11 Nov 2020 20:47:12

US3732311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:24:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:33:20
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	11 Nov 2020 20:47:12

US3732311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:24:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:33:20
User entered 'three times daily (TID)'	Amara Yilmaz (b) (4) (b) (4)	11 Nov 2020 20:47:12

**US3732311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:24:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:33:20
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	11 Nov 2020 20:47:12

**US3732311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:24:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:33:20
User entered 'Oral (ORAL)'	Amara Yilmaz (b) (4) (b) (4)	11 Nov 2020 20:47:12

**US3732311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:24:11**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:33:20
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	11 Nov 2020 20:47:12



**US3732311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:24:11**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:33:20
User entered '18 Sep 2020'	Amara Yilmaz (b) (4) (b) (4)	11 Nov 2020 20:47:12

**US3732311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:24:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 23:33:20
User entered '0'	Amara Yilmaz (b) (4)	11 Nov 2020 20:47:12
	(b) (4)	

US3732311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:24:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 23:33:20
User entered 'No (N)' reason for change: New Information		24 Nov 2020 17:27:16
User entered 'Yes (Y)'	Amara Yilmaz (b) (4)	11 Nov 2020 20:47:12
	(b) (4)	

US3732311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:24:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 23:33:20
User entered '22 Oct 2020' reason for change: New Information		24 Nov 2020 17:27:16
User entered empty.	Amara Yilmaz (b) (4)	11 Nov 2020 20:47:12
	(b) (4)	

US3732311

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:24:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 23:33:20
User entered 'No (N)' reason for change: Data Entry Error		24 Nov 2020 17:27:16
User entered 'Yes (Y)'	Amara Yilmaz (b) (4)	11 Nov 2020 20:47:12
	(b) (4)	

**US3732311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:24:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	11 Nov 2020 20:47:12

US3732311

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:24:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 20:47:12

**US3732311**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:24:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Nov 2020 20:47:12



US3732311

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 12 Aug 2021 13:24:11

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:32:05
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:13:47
User entered 'Yes (Y)'	Amara Yilmaz (b) (4) (b) (4)	09 Nov 2020 21:44:22

US3732311

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 12 Aug 2021 13:24:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 23:14:05
User entered '05 Oct 2020'	Amara Yilmaz (b) (4)	09 Nov 2020 21:45:00
	(b) (4)	

US3732311

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 12 Aug 2021 13:24:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:14:05
User entered 'bilateral breast implant removal and left pectoral muscle repair'	Amara Yilmaz (b) (4) (b) (4)	09 Nov 2020 21:45:00

US3732311

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 12 Aug 2021 13:24:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
User closed query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 18:57:27
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 23:14:05
Query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification.' answered with 'AE updated ' (Site from DM).	Lauren Arnett (b) (4)	02 Dec 2020 17:24:23
User opened query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 15:11:14
User entered 'Adverse Event (AE)'	Amara Yilmaz (b) (4)	09 Nov 2020 21:45:00

US3732311

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 12 Aug 2021 13:24:11**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 23:14:05
User entered empty.	Amara Yilmaz (b) (4) (b) (4)	09 Nov 2020 21:45:00

**US3732311**

**Folder: End of Study (1)**

**Form: Dosing Discontinuation**

**Generated On: 12 Aug 2021 13:24:11**

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:25:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:29:18
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
User entered '08 Oct 2020'	(b) (4) Lauren Arnett (b) (4) (b) (4)	14 Dec 2020 16:59:55

US3732311

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:24:11

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:25:55
DataPoint Verified.	(b) (4), (b) (6)	24 Mar 2021 21:29:18
User signature succeeded.	Scott Overcash (b) (4)	26 Feb 2021 01:41:25
User entered 'AE (specify) (ADVERSE EVENT)'	Lauren Arnett (b) (4)	14 Dec 2020 16:59:55

US3732311

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:24:11

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)	27 Apr 2021 07:25:55
User signature succeeded.	Scott Overcash (b) (4)	09 Apr 2021 21:46:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 21:29:18
User closed query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' (Site from DM).		15 Mar 2021 16:38:24
Query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' answered with 'data has been updated ' (Site from DM).	Amara Yilmaz (b) (4) (b) (4)	10 Mar 2021 17:25:20
Signature has been broken.	Amara Yilmaz (b) (4) (b) (4)	10 Mar 2021 17:25:11
User entered 'AE #2' reason for change: Per Query Resolution	Amara Yilmaz (b) (4) (b) (4)	10 Mar 2021 17:25:11
User opened query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:17:28
User signature succeeded.	Scott Overcash (b) (4) (b) (4)	26 Feb 2021 01:41:25
User entered 'SUBJECT DECISION TO NOT HAVE SECOND DOSE OF STUDY DRUG DUE TO AE OF displaced left breast silicone implant' reason for change: Per Query Resolution	Lauren Arnett (b) (4) (b) (4)	14 Dec 2020 17:23:13
User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	14 Dec 2020 17:01:24
User entered 'subject decision to not have second dose of study drug due to AE of LEFT AXILLARY LYMPHADENOPATHY AT INJECTION SITE' reason for change: Per Query Resolution	Lauren Arnett (b) (4) (b) (4)	14 Dec 2020 17:01:24



US3732311

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:24:11

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System). User entered empty.	System	14 Dec 2020 16:59:55
	Lauren Arnett (b) (4) (b) (4)	14 Dec 2020 16:59:55